# NEWDIGS LEAPS DESIGN LAB
***July 17 & 18, 2018, Cambridge, MA***
## BIOGRAPHICAL SKETCHES

**Brian Alexander, MD, MPH**
Disease Center Leader, Radiation Oncology
Center for Neuro-Oncology
Dana-Farber Cancer Institute

Brian Alexander, MD, MPH is an Associate Professor of Radiation Oncology at Harvard Medical School and leads radiation oncology at Brigham and Women's Hospital and the Dana-Farber Cancer Institute. Dr. Alexander is head of the DFCI Program for Regulatory Science and is Deputy Director of the Harvard/MIT Center for Regulatory Science. He serves as the PI of INSIGhT, an adaptive platform trial for glioblastoma, and is the President/CEO of the Agile Research Foundation that sponsors the GBM AGILE global platform trial in development. Brian is a graduate of Kalamazoo College, the University of Michigan Medical School, the Harvard School of Public Health, and served as a White House Fellow.

**Shada Alsalamah, PhD, MSc**
Assistant Professor, King Saud University
Visiting Scholar, Media Lab
Massachusetts Institute of Technology

Dr. Shada Alsalamah is an Assistant Professor of Healthcare Information Systems Security at King Saud University. She is currently a Visiting Scholar at the Media Lab, MIT, joining Prof. Alex "Sandy" Pentland's Human Dynamics group. In 2017, she has become Vice President, mHealth Solutions Division, AnmarIT and a year later a Chief Health Info and Security Officer, MedEra. Through her work, she contributes to the global healthcare sector modernization movement by developing secure, mobile, and intelligent solutions for emerging healthcare delivery models using Blockchain and Open Algorithms. Dr. Alsalamah has been a keynote speaker at a number of international events.

**Naomi Aronson, PhD**
Executive Director
Clinical Evaluation, Innovation, and Policy
Blue Cross Blue Shield Association (BCBSA)

Dr. Naomi Aronson leads BCBSA clinical effectiveness and policy engagement with government, regulatory agencies and policy consortia. Her areas of leadership include comparative effectiveness, patient centered research, safety surveillance, regulatory science and methodological standards. Previously, Dr. Aronson led the development of the BCBSA Technology Evaluation Center (TEC), now Evidence Street™ (ES), as a nationally recognized technology assessment program and an Evidence-based Practice Center (EPC) of the Agency for Healthcare Research and Quality (AHRQ).

She is a member of the Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI), the Health Technology Assessment International Health Policy Forum, the National Academy of Medicine Genomics Roundtable, the National Business Group on Health Committee on Evidence-Based Benefit Design, the New Drug Development Paradigms (NEWDIGS) initiative of the MIT Center for Biomedical Innovation, Steering Committee of the Quality Assurance Pilot for Cancer CDx, Member Clinical Trials Transformation Initiative (CTTI) Real World Evidence (RWE) Project Team, and the Medical Device Innovation Consortium (MDIC) National Evaluation System for Health Technology (NEST) Governing Committee.

Dr. Aronson is a founding member of EXCITE International. She serves on the EXCITE International Advisory Board, the Scientific Collaboration and is Chair of the Payer Advisory Committee.

Prior to joining BCBSA, Dr. Aronson was a member of the Northwestern University faculty, specializing in the sociology of science and medicine. She also was a post-doctoral fellow in the Science, Technology and Society Program at the Massachusetts Institute of Technology

**Robyn L. Ball, PhD**
Clinical Data Scientist
Roam Analytics

Dr. Robyn Ball is a Clinical Data Scientist at Roam Analytics, where she leverages Roam's data and machine learning assets to create analyses of patient pathways through disease and treatment progression. Dr. Ball earned her Ph.D. in Statistics from Texas A&M University. She has conducted biomedical research as a NASA fellow and as an intern at UT MD Anderson Cancer Center, developed novel computational methods for genomic data at The Jackson Laboratory in Bar Harbor, Maine, and was most recently a Senior Biostatistician at Stanford University where she collaborated with medical researchers on studies that posed methodological challenges.

**Stella Blackburn, MSc, MB, MA, FRCP**
Vice President Real-World Evidence Solutions, IQVIA
Research Affiliate, MIT Center for Biomedical Innovation: NEWDIGS

Dr. Stella Blackburn is currently Vice President, Global Head of Early Access & Risk Management at QuintilesIMS. She joined Quintiles in April 2014 after spending more than 25 years working in pharmacovigilance and pharmacoepidemiology in regulatory and pharmaceutical industry environments. Following medical training at Cambridge University and Guy's hospital, Dr. Blackburn worked in hospital medicine before joining the pharmaceutical industry. There, she spent 11 years working in pharmacovigilance and pharmacoepidemiology, gaining an MSc in Epidemiology from the London School of Hygiene and Tropical Medicine. She left Ciba Pharmaceuticals in 1997 to join the European Medicines Agency (EMA) where she stayed for almost 17 years in a variety of pharmacovigilance and pharmacoepidemiology posts. For the last 10 years at the EMA, she was responsible for developing EU policy on risk management, writing the EU guidelines on this topic and more recently as part of the core team helping to implement the 2010 PhV legislation. She was part of the original steering group developing the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) and was the Alternate Co-ordinator, and a scientific work package leader, of PROTECT. Dr. Blackburn is a Fellow of the International Society of Pharmacoepidemiology (ISPE), the Royal College of Physicians of Edinburgh and the Faculty of Pharmaceutical Medicine. She is a past President of ISPE – the first regulator to hold this post – and an honorary lecturer at the London School of Hygiene and Tropical Medicine.

**Mary T. Brophy, MD**
Director of Operations,
Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC)
Veterans Affairs Boston Healthcare System

Mary Brophy, MD, MPH, completed her residency and fellowships in Hematology and Oncology at the VA Medical Center in Boston, Massachusetts, and has remained there throughout her career. Dr. Brophy co-founded the Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC), and now serves as a Director. In 2008, MAVERIC was awarded national 'Transformative Initiatives': The Point of Care Research Program and the Million Veteran Program, two programs for which Dr. Brophy serves as an Investigator. These projects intersect at the junction of clinical care, research, and learning healthcare system activities.

Dr. Brophy also has an extensive background in the development of large-scale, national-level laboratory programs for the VA, and is the Director of the VA Central Biorepository. As a past Acting Director of the Boston Cooperative Studies Coordinating Center, Dr. Brophy now serves on numerous Executive Committees and Planning Committees for CSP studies.

Dr. Brophy is currently the Director of the VISN1 Clinical Trials Network, an initiative to expand research and increase Veteran enrollment in clinical trials across the New England VA system. She continues to treat patients as an Attending Hematologist/Oncologist at the VA Boston Healthcare System.

**Kim A. Caldwell, RPh**
Vice President - Pharmacy Professional Affairs
Humana Pharmacy Solutions

In his role as Vice President for Pharmacy Professional Affairs, Kim leads two unique business functions. He leads one team of focused colleagues who serve to liaison between HPS business owners, Humana Public Affairs, and key professional and trade partners. They serve as the pharmacy subject matter experts aligned with key business, legislative, and regulatory issues.

Kim's second group, Comprehensive Health Insights, Inc., is Humana's evidence-based research team. Among other tasks, Mr. Caldwell gets to influence the business's focus on key healthcare questions in collaboration with selected private, public, and internal research and data partners.

Mr. Caldwell is recognized by many for his work while helping to lead the development and implementation of Part D – the Medicare prescription drug benefit. During 2004-2005, Kim served the Centers for Medicare and Medicaid Services (CMS) as Division Director - Clinical and Economic Performance in the Center for Beneficiary Choices (CBC).

He has extensive experience throughout the practice of pharmacy ranging from owner/operator of a small independent pharmacy to senior leadership positions within health plans and PBMs. Among other opportunities, Kim has worked in long-term care consulting, electronic prescribing, and the pharmaceutical manufacturing industry. In addition to his work with CMS, Mr. Caldwell's professional service through government includes more than 12 years on the Texas State Board of Pharmacy.

**Tanisha V. Carino, PhD**
Executive Director
FasterCures
Milken Institute

Tanisha Carino, Ph.D., the respected senior executive with more than two decades of experience in academia, government, and the private sector, joined the Milken Institute as executive director of *FasterCures*, the center devoted to saving lives and improving the medical research system. Throughout her distinguished career, Dr. Carino has been at the forefront of collaborative efforts to promote policies, research, and business practices that support the fight against disease and improve the lives of patients. She most recently led the U.S. policy function for GlaxoSmithKline, a U.K.-based science-led global healthcare company. Prior to her role at GlaxoSmithKline, she spent more than a decade with Avalere Health, where, among other responsibilities, she founded the Center on Evidence Based Medicine and worked with patients, government, and senior leaders at Fortune 500 companies to maximize opportunities and mitigate challenges related to biomedical research and patient access. Prior to Avalere, Dr. Carino worked in the Medicare program to improve access for its beneficiaries and support the development of real-world evidence. Dr. Carino earned her Ph.D. in health policy from Johns Hopkins University in Baltimore and is associate faculty at the Johns Hopkins Bloomberg School of Public Health. She also completed a Fulbright fellowship in The Netherlands, where she was based at The Institute for Technology Assessment and Department of Health Policy and Management at Erasmus University. During her fellowship, she studied how global institutions make technology and health care decisions and investments. Her research was published in the volume Health Care Coverage Determinations: An International Comparative Study. Since then, she has been widely published on topics that include patient engagement and paying for cures. She holds a B.A. in sociology from Emory University in Atlanta.

**Marissa Carroll, MPH**
Research Associate
Real-World Evidence
Evidera

Marissa Carroll, MPH, is a Research Associate III with the Real-World Evidence team at Evidera. In her role at Evidera, Ms. Carroll prepares strategic recommendations regarding evidence planning and evidence generation to address stakeholder needs for market access. Ms. Carroll is skilled at utilizing creative approaches to identify relevant information from various sources to support the enhancement of value propositions for emerging health technologies with significant disruptive potential such as personalized medicine, diagnostics, orphan drugs, cell therapy and regenerative medicine. In addition, Ms. Carroll is an experienced strategic program manager. Her responsibilities as a program manager include developing and reviewing deliverables, providing strategic oversight, maintaining timelines and budgets, and leading the day-to-day operations of the program. In addition, she is skilled at consolidating and coordinating timely feedback from multiple stakeholders. Ms. Mihos received her BS in business administration and finance from the University of Vermont in Burlington, Vermont, and her MPH from Boston University's School of Public Health. Her position prior to joining Evidera was as a senior associate at a leading financial institution.

**Michael Ciarametaro, MBA**
Vice President of Research
National Pharmaceutical Council

Michael Ciarametaro serves as the National Pharmaceutical Council's vice president of research. In this position, Mr. Ciarametaro plays a key role in developing and delivering NPC's portfolio of health policy and health outcomes projects.

Mr. Ciarametaro has 13 years of health care industry experience with both pharmaceutical manufacturers and payers. Most recently, he was a senior research manager at Evidera, where he designed and led a wide variety of both qualitative and quantitative studies across multiple health care industries and stakeholders. Mr. Ciarametaro's work analyzed reimbursement and treatment patterns for drugs, biologicals and devices. Prior to Evidera, he served as a financial analysis manager at WellPoint NextRx and as lead staff at Noblis, a nonprofit science, technology and strategy organization.

Mr. Ciarametaro holds a Bachelor of Science from the University of Virginia and received his MBA from George Mason University.

**Jan Cook, MD, MPH**
Vice President
Senior Medical Director
Harvard Pilgrim Health Care

Dr. Cook is the Vice President, Senior Medical Director of Harvard Pilgrim Health Care (HPHC). She is responsible for clinical oversight of medical expense initiatives; medical policy development and implementation; UM and medical benefit pharmaceutical programs and other medical director functions. Prior to joining HPHC, Dr. Cook spent four years as the Chief Medical Officer of Minuteman Health, a startup health plan in Massachusetts and New Hampshire. Previous positions include medical director roles at Blue Cross Blue Shield of Massachusetts and the Mind Body Medical Institute in Boston. She is a board-certified internist and a former primary care provider. Her current clinical interests are building resiliency in patient populations, including those involved in palliative care programs.

**Nick Crabb PhD**
Program Director
Scientific Affairs
National Institute for Health and Care Excellence (NICE)

Nick had a 20 year career in analytical science, process technology and general management in the chemical, pharmaceutical and contract laboratory industries prior to joining NICE as the associate director for the Diagnostics Assessment Programme in 2010. Nick was responsible for the establishment and management of the programme. In 2014 Nick was appointed Programme Director for Scientific Affairs where he oversees NICE Scientific Advice, the Science Policy and Research programme and the NICE Office for Market Access. Nick is also leads NICE's contribution to the European HTA network – EUnetHTA..

**Mark J. Cziraky, PharmD, CLS**
Vice President of Research
HealthCore

Mark J. Cziraky, PharmD, CLS, is the co-founder and Vice President of Research at HealthCore. Dr. Cziraky is currently responsible for the operational oversight of the Life Sciences Research business, and serves as key architect in creating unique, multi-stakeholder research collaborations within the healthcare industry. Dr. Cziraky has Fellowship status in the American Heart Association and the National Lipid Association and is accredited as a Clinical Lipid Specialist by the Accreditation Council for Clinical Lipidology. Dr. Cziraky serves as a member of the Board of Trustees for the Institution of Safe Medication Practice, The Board of Directors of MedERRS and the Board of Directors for the National Lipid Association. He is currently the Chair of the Planning Committee for the Biologics and Biosimilars Collective Intelligence Consortium and Chair of the Institutional Council of The International Society of Pharmacoeconomics and Outcomes Research. He is also a member of the Diabetes Measurement Advisory Panel for the National Committee for Quality Assurance, and recently completed two terms on American Pharmacists Association Foundation Board and served for five years as a member of the Cardiology Expert Committee for the United States Pharmacopeia.

**Erica D'Agostino**
Executive Director
The Arthritis Foundation

Erica D'Agostino is the Executive Director of New England for the Arthritis Foundation and has been for the last 2 years. Before coming to the Arthritis Foundation she spent 3 years at The Genesis Foundation for Children and 9 years working for Autism Speaks. Erica has always had a passion for working in the non-profit sector, raising money and championing advocacy on behalf of disorders and diseases that affect the general population. Her position at

the Arthritis Foundation has allowed her the opportunity to take on a platform that is particularly close to her heart. Erica is a graduate of Simmons College and lives in Framingham with her husband and 2 children.

**Timothy Dasey, PhD**
Leader
Informatics and Decision Support Group
MIT Lincoln Laboratory

Dr. Timothy Dasey is the Leader of the Informatics and Decision Support Group at MIT Lincoln Laboratory. The Group supports multiple missions, leading programs in homeland security, transportation systems, and biomedical systems, and providing machine learning and human-machine system analysis skills that are used across Lincoln Laboratory (e.g. autonomous systems, cybersecurity, ISR).

Previously Dr. Dasey was the leader of the Chemical and Biological Defense (CBD) Systems Group, and a manager in the Weather Sensing Group, both at MIT Lincoln Lab.

Tim holds a Ph.D. degree in Biomedical Engineering from Rutgers University and a B.S. in Electrical and Computer Engineering from Clarkson University.

**Kourtney Davis, PhD, MSPH**
Senior Director
Head, Real World Data and Analytics
GlaxoSmithKline

Dr. Kourtney Davis is currently Senior Director and Therapy Area Lead for Respiratory Epidemiology at GlaxoSmithKline R&D. She leads a team of eight Respiratory epidemiologists based in the US and UK, as well as Regional Epidemiology Directors based in Singapore (Asia Pacific) and Brazil (Latin America). Dr. Davis has spent the last 16 years of career with GSK and worked on epidemiology programs supporting the development programs, regulatory submissions and post-authorization evaluations for more than ten medicines with indications for COPD, asthma or rhinitis. She has worked across three sites: RTP (11 years), Wavre, Belgium (4 years) and is now based in Upper Providence. Dr. Davis earned a MSPH and PhD in epidemiology from the University of North Carolina at Chapel Hill and is an adjunct assistant professor of epidemiology with the UNC Gillings School of Global Public Health. She has collaborated with academic partners and public-private consortia across US, EU, Latin America, and Asia Pacific. Dr. Davis has strived to develop real world data and analytical capabililties to increase understanding of respiratory disease, including recently leading the collaboration with Oxford University to develop the fifth of the 'Big 5 chronic disease' areas of focus on COPD with the Kadoorie China Biobank cohort and serving as the GSK primary contact for COPD 360, the COPD Foundation's Patient Powered Research Network funded by PCORI. She has published extensively on the epidemiology and burden of respiratory disease, real world use of respiratory medications and their effects in populations.

**Felipe Dolz, DVM, PhD**
Head
Global Regulatory Science and Policy
Sanofi

Felipe Dolz, DVM, Ph.D., is the Head of Global Regulatory Science and Policy at Sanofi.

Felipe's regulatory affairs career, expanding over 27 years, started in animal health where he held a number of positions of increasing responsibility at the country, regional and global level first in Europe and during the last several years in the US. Before taking his current position, he led the Global Regulatory, CMC & Pharmacovigilance group for Merial, the animal health division of Sanofi. Throughout his career, he has been instrumental to the successful development and approval of a number of products, including both drugs and vaccines, around the world.

In his current position, he is responsible for providing leadership and strategic direction to the Global Regulatory Science and Policy organization across Sanofi divisions and geographies. He represents the company in national and international fora and associations.

Felipe is a member of a number of organizations and is closely involved in initiatives that promote the partnership between Academia, Industry and Health Authorities around the world. He earned his Doctor of Veterinary Medicine (DVM) degree specializing in Health and Medicine, and his Ph.D. (cardiology) at Universidad Complutense de Madrid (UCM) in Spain.

**Hans-Georg Eichler, MD, MSc**
Senior Medical Officer
European Medicines Agency

Dr. Hans-Georg Eichler is the Senior Medical Officer at the European Medicines Agency in London, United Kingdom, where he is responsible for coordinating activities between the Agency's scientific and public health issues. Dr. Eichler is a former member of the Agency's Committee on Orphan Medicinal Products and Scientific Advice Working Party. Prior to joining the European Medicines Agency, Dr. Eichler was at the Medical University of Vienna in Austria for 15 years. He was vice-director of Research and International Relations since 2003, and professor and chair of the Department of Clinical Pharmacology since 1992. His other previous positions include president of the Vienna School of Clinical Research and co-chair of the Committee on Reimbursement of Drugs of the Austrian Social Security Association. His industry experience includes time spent at Ciba-Geigy Research Labs, UK, and Outcomes Research at Merck & Co., in New Jersey.

**John Ferguson, MD**
Head, Genzyme PV Unit
Global Pharmacovigilance and Epidemiology
Sanofi US

Dr. Ferguson is a board certified Cardiologist and former co-principal NIH and the MRCC investigator.

He received his training in Cardiology and Clinical Epidemiology at McGill University, McMaster University and Cedars-Sinai Medical Center.

Prior to entering the pharmaceutical industry, his research focused on risk prediction in coronary artery disease and developing novel approaches to cerebrovascular disease, including carotid stenting and cerebral fibrinolysis.

Dr. Ferguson has served as a panelist and benefit-risk key subject matter expert for the Institute of Medicine (IOM).

His current work with industry groups, regulators and academic institutions focuses on structured benefit-risk optimization, real world evidence, patient preferences and adaptive product development.

**Ryan E. Ferguson, ScD, MPH**
Director, Cooperative Studies Program Coordinating Center
Veterans Affairs Boston Healthcare System

Dr. Ryan Ferguson is the Director of the VA Cooperative Studies Program Coordinating Center in Boston, MA, where he specializes in the design and conduct of large multi-center randomized clinical trials. Dr. Ferguson joined the Cooperative Studies Program in 2001 and has since focused on clinical trial methodologies for conducting pragmatic comparative effectiveness trials. He currently serves as a Co-Principal Investigator for the VA's Point of Care Research Program which is focused primarily on pragmatic clinical trials and innovation in translational science. In addition to his interests in clinical trials methodology and pragmatic trials, Dr. Ferguson's research interests are focused on the epidemiology of acute kidney injury and chronic kidney disease, as well as the molecular epidemiology of cancer. Dr. Ferguson has also led research projects aimed at improving our understanding cardiovascular disease outcomes in the veteran population and at improving prediction of medication compliance in patients treated in the VA. Dr. Ferguson's published work includes first authored publications, abstracts, presentations and book chapters on pragmatic trials. Several of his publications have been published in top-tier medical journals including the New England Journal of Medicine, the Annals of Internal Medicine, and the Journal of the American Medical Association. Dr. Ferguson is on faculty at Boston University School of Medicine where he is a Research Assistant Professor in the Section of General Internal Medicine. He is also a member of the Society for Clinical Trials, the Society for Epidemiologic Research, and the American Statistical Association.

**Louis Fiore, MD, MPH**
Executive Director
Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC)
Veterans Affairs Boston Healthcare System

Dr Louis Fiore is a Physician-scientist-manager-innovator with board certifications in internal medicine, oncology and hematology.

He is currently the Executive Director of a 140 person research enterprise within the Department of Veterans Affairs. The Center (MAVERIC) provides the Department nationally with expertise in large scale clinical trials, epidemiological studies, biobanking and biomedical informatics.

The Center is also responsible for three of the four VA national research 'Transformative Initiatives': the Million Veteran Program (MVP); the Genomic Information System for Integrated Science (GenISIS) and the Point of Care Research Program.

The MVP is attempting to enroll 1 million users of the VA system to participate in a cohort designed for discovery and validation of genomic knowledge. Participants donate blood for genomic analysis and agree to share their medical record data and other personal information with researchers. GenISIS is the computational platform that will allow for subject recruitment and enrollment, data warehousing and scientific computation. Thee platform is being designed and implemented at MAVERIC by the informatics team (see below).

Dr Fiore's current passion is embodied by the final Transformative Initiative, the Point of Care Research Program. This national project uses innovative health informatics to enable the conduct of clinical research in the clinical care ecosystem to create a 'learning healthcare system'. Both pilot and mature studies are underway and in planning.

**Patrick J. Fowler, MBA**
Head of Strategy and Operations
Sanofi

Patrick is a biotechnology executive at Genzyme Sanofi. He has 12 years of experience in Corporate Development, Business Development and Commercial Operations in a variety of therapeutic spaces including rare disease, autoimmune and inflammation, musculoskeletal and hematology/oncology. He has extensive experience in Mergers & Acquisitions, Licensing, Divestitures and Drug/Device Development. Prior to joining Genzyme Corporation in 2006, Patrick was a scientist in the medical device industry and contributed to the development of the Cypher drug-eluting stent.

Patrick has a background in Genetics & Molecular Cell Biology. His thesis topic was the infectivity of HIV in reproductive tract epithelial cells using RT-PCR. He also has an MBA from the University of Toronto.

**Steven Fox, MD, MSc**
Assistant Professor of Pharmacy, Medicine and Pediatrics
School of Pharmacy
University of Southern California

Dr. D. Steven Fox is an assistant professor of Pharmacy, Medicine, and Pediatrics at the University of Southern California's School of Pharmacy. He is also a clinical fellow at the University's Schaeffer Center for Health Policy, and a physician specialist at the LAC+USC Medical Center. His background and training span clinical medicine, health economics, quantitative policy analysis, public health, and atmospheric physics. His current research focuses on improving healthcare and health policy decision-making by optimizing use of available data. He was previously an assistant policy researcher at the RAND Corporation, a financial analyst for private equity investing, and a consulting specialist for the LA County Department of Health Services.

**David P. Fritsche, MBA**
Technology Officer, LEAPS
Center for Biomedical Innovation: NEWDIGS
Massachusetts Institute of Technology

David (Dave) Fritsche is the Technology Officer for the LEAPS program, leading the effort to identify, evaluate and implement appropriate technologies to support the LEAPS initiative. Dave is also founder and Managing Director of Pantograph Group, providing IT strategy and consulting for the biopharma industry. Prior to joining the LEAPS program, Dave worked at ARIAD Pharmaceuticals as Vice President, Global Head of IT for the Clinical through Commercial business areas. He was responsible for the information systems supporting patient access to treatments through the functions of clinical development, medical affairs, pharmacovigilance, and commercial operations. Prior to joining ARIAD, Mr. Fritsche served as Sanofi's Global IT Business Partner in support of scientific core platforms, including lead compound generation, pharmaceutical development, preclinical, and clinical. Prior to that, he co-led the data migration of all Genzyme and Sanofi-Pasteur safety data into the global Sanofi pharmacovigilance system. Previously, Mr. Fritsche was with Genzyme for ten years. Starting with EDC implementations for clinical trials and culminating with deployment of an industry-recognized platform for rare disease registries, he steadily gained responsibility for systems supporting clinical development, registration and post-marketing support. Mr. Fritsche earned a B.A. in Computer Science from the University of Delaware and an M.B.A. in Marketing from the University of Rochester.

**R. John Glasspool**
Research Affiliate and Senior Advisor, FoCUS
Center for Biomedical Innovation: NEWDIGS
Massachusetts Institute of Technology

John Glasspool is a member of the Board of Directors of Dalcor Corporation. He was formerly the Executive Vice President, Head of Corporate Strategy and Customer Operations at Baxalta Incorporated, formerly Baxter BioScience. Prior to joining Baxter in August 2012, John was Head Region Europe and Novartis Vaccines & Diagnostics (V&D), a member of the V&D Executive Committee. John served as a board member, Vice President and President of the European Vaccine manufacturers (EVM), from 2010 until December 2012. Previously, John was Head of Global Pricing & Market Access, and Head of Global Commercial Operations in Novartis Pharma, where he led the functions in embedding the needs of customers and consumers for brands at all stages of their lifecycle -- development, launch and in market. John joined Novartis Head of Marketing for NeuroScience. He was promoted to Global Head CardioVascular & Metabolism Business Franchise in 2006, during which time he grew the franchise sales from $4.9 Bn in 2004 to $6.7 Bn over a three-year period. Before joining Novartis, John worked for J&J in Pharmaceuticals and Consumer, launching products in the Europe, US, and for J&J Corporate in Global Strategic Marketing. John held a number of positions with J&J during his career there including hospital sales, project and product manager, before becoming the Neurology Business Head responsible for marketing & sales and then Neurology European Business Director. Prior to working at J&J, John worked at a small startup company selling ethical products to GP's and a range of over the counter products to pharmacies. Before joining the pharmaceutical industry, John owned a restaurant and small hotel. While always holding commercial roles, John has been granted 2 patents. One is in neuroscience on "statin therapy for enhancing cognitive maintenance" (EP 1 492 539 B1) by European Patent Office on 28 June 2003. This patent relates to a method of treating dementia as a result of Alzheimer's Disease, or a memory disorder. The other one is in cardiovascular on the "use of iron chelator for the treatment of myocardial infarction" by World Intellectual Property Organization on 20 November 2008.

**Cynthia Grossman, PhD**
Director, Science of Patient Input
FasterCures
Milken Institute

Dr. Cynthia (Cyndi) Grossman is director at *FasterCures,* a center of the Milken Institute, leading efforts to improve health by expanding opportunities for patients' perspectives to shape the processes by which new therapies are discovered, developed and delivered. Prior to joining *FasterCures*, Dr. Grossman was chief of the HIV Care Engagement and Secondary Prevention Program at NIH where she worked to define the social and behavioral scientific agenda for the development and clinical testing of microbicides as HIV prevention and HIV cure related research. Dr. Grossman graduated Phi Betta Kappa from Earlham College with a BA in psychology and biology and earned her PhD in clinical psychology from the University of Vermont.

**Gigi Hirsch, MD**
Executive Director, Center for Biomedical Innovation and Program Director, NEWDIGS
Massachusetts Institute of Technology

Dr. Gigi Hirsch is the Executive Director of the MIT Center for Biomedical Innovation (CBI) which designs and leads collaborative research programs designed to improve global health by overcoming challenges to the development, diffusion and adoption of biomedical innovation. Her current efforts at CBI largely center on leading the New Drug Development Paradigms initiative (NEWDIGS), a unique "think and do tank" focused on re-engineering key elements of the global biomedical innovation ecosystem to deliver new, better, affordable therapeutics to the right patients faster. NEWDIGS' first program focused on aligning stakeholders around more adaptive approaches to the management of risk and uncertainty in pharmaceutical regulation, and helped to inspire the Medicines Adaptive Pathways to Patients (MAPPs) pilot program launched by the European Medicines Agency in March 2014. NEWDIGS provided a pre-competitive collaboration environment for case-based simulations of adaptive licensing involving global regulators, payers, health technology assessment officials, biopharmaceutical companies, providers, patients, and academic researchers. Its methodologies offer an emerging model for research-driven policy and process change, highlighted through Dr. Hirsch's invited participation as an Expert Advisor to the US President's Council of Advisors on Science & Technology (PCAST) in 2011-2012. Dr. Hirsch has held a number of leadership roles that leverage her broad clinical background (internal medicine, emergency medicine, and psychiatry) along with her passion for innovation, entrepreneurship, and improving clinical outcomes. Prior to joining CBI, she served as Director of Academic and Professional Relations at Millennium Pharmaceuticals, and was founder and CEO of a boutique entrepreneurial venture (MD IntelliNet) launched with seed funding from Boston's Beth Israel Hospital. She held faculty appointments at Harvard Medical School (Internal Medicine and Psychiatry), Brown University (Internal Medicine), and

served as an attending physician in the Emergency Department at Brigham and Women's Hospital after receiving her medical degree at the University of Cincinnati.

**Tom Hubbard, MPP**
Vice President of Policy Research
Network for Excellence in Health Innovation (NEHI)

Tom Hubbard leads NEHI's projects on comparative effectiveness research, patient medication adherence, and prevention and wellness initiatives. Mr. Hubbard leverages his policy and technology experience to examine ways the country's health care system can be transformed, focusing on the promotion of medical innovation and the improvement of quality and efficiency in clinical care.

Mr. Hubbard came to NEHI after seven years at the Massachusetts Technology Collaborative (MTC), where he led industry-focused projects and supervised the annual publication of the MTC Index of the Massachusetts Innovation Economy. His work has included supervising the I-495 Technology Corridor Partnership, an industry-municipal collaboration on growth, and leading projects on broadband deployment, federal research funding advocacy, and nanotechnology.

Previously, Mr. Hubbard served as Executive Assistant for Economic Affairs to U.S. Senator John Kerry, as Deputy Director of Development for Massachusetts Governor Michael Dukakis, and as Director of Community Development and Planning for the City of Gardner, Massachusetts.

Mr. Hubbard graduated from Harvard College and holds a masters in public policy from Harvard's Kennedy School of Government.

**Javier Jimenez, MD, MPH**
VP Global Head
Real World Evidence and Clinical Outcomes
Sanofi

**Anne Kim**
Graduate Student Researcher
Pentland Group
MIT Media Lab

Anne Kim is a researcher and graduate student specializing in Computer Science and Molecular Biology at MIT. Professor Alex "Sandy" Pentland, head of the Human Dynamics Group at the MIT Media Lab, is the advisor for her thesis focusing on blockchain solutions for clinical trial optimization. Outside of her thesis work, Anne has done a number of different projects in quantum chemistry simulations, genome-wide association studies, natural language processing for electronic health records, and a startup in secure data sharing. Anne sees accessibility to healthcare as a right, and believes that the interface between biology, healthcare policy, and technology is a promising way to achieve that mission.

**Kay Larholt, ScD**
Director of Integrated Knowledge Solutions, NEWDIGS
Center for Biomedical Innovation
Massachusetts Institute of Technology

Kay M. Larholt ScD is Director of Integrated Knowledge Solutions, NEWDIGS at MIT Center for Biomedical Innovation. Dr. Larholt worked as a biostatistician in the pharmaceutical/biotechnology industry for 18 years beginning her career at R.W. Johnson Pharmaceutical Research Institute, where she spent 12 years in positions of increasing responsibility, ultimately serving as Director, Clinical Biostatistics. Following her years at J&J, Dr. Larholt worked at Genzyme Corporation and at Boston Scientific. In 2006, Dr. Larholt joined Abt Bio-Pharma Solutions where she was responsible for overseeing the design, operation, and management of clinical trials and prospective observational studies. Most recently, Dr Larholt was Head of Late Phase Research Operations at HealthCore, Inc., where she designed and implemented Pragmatic Clinical Trials and prospective observational studies. Dr. Larholt holds a ScD in biostatistics from Harvard University.

**Sarah Leatherman, PhD, MA**
Associate Center Director
Point of Care Program
US Department of Veterans Affairs, Boston

Dr. Sarah Leatherman is the Associate Director of the VA Cooperative Studies Program Point-of-Care Program in Boston, MA, where she oversees the design and conduct of embedded pragmatic clinical trials. Dr. Leatherman joined the Cooperative Studies Program in 2010 and has since focused on implementation of pragmatic comparative effectiveness trials and promotion of a learning healthcare system within the VA. As a trained biostatistician, she also oversees the analytical integrity of the multiple databases required to execute these activities. Dr. Leatherman's published work includes first authored publications, abstracts, and presentations on pragmatic trials. She is also a member of the Society for Clinical Trials, the American Statistical Association, and the Caucus for Women in Statistics.

**Christopher Leptak, MD, PhD**
Co-Director, Biomarker Qualification Program,
Biomarker and Companion Diagnostic Lead, Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
US Food and Drug Administration (FDA)

Chris Leptak, MD, PhD, completed his MD and PhD in microbiology/immunology at UCSF. After residency in Emergency Medicine at Harvard's combined Mass General and Brigham program, he joined FDA in 2007 as a primary reviewer in OND's division of gastroenterology products, focusing on immunomodulators for inflammatory bowel diseases. In 2010, he joined OND's Guidance and Policy Team and became OND's Biomarker and Companion Diagnostics Lead. His focus is on biomarker and diagnostic device utility in clinical trials and drug development, both for drug-specific programs as well as serving as Director of CDER's Biomarker Qualification Program. He is also Director of OND's Regulatory Science Program which aims to improve regulatory consistency and policy development in areas of emerging science and technology.

**Robyn Lim, PhD**
Senior Scientific Advisor
Office of Legislative and Regulatory Modernization
Health Canada, Health Products and Food Branch

Dr. Lim is Senior Science Advisor with the Office of Legislative and Regulatory Modernization, Health Products and Food Branch, Health Canada, and has provided technical, review-related perspectives to the development of Canada's modernized drug regulatory system since the project's inception in late 2005. She developed the concepts for the Health Canada's Progressive Licensing proposal and for the Department's new benefit-harm-uncertainty management approach. Dr. Lim was previously with Health Canada's Therapeutic Products Directorate, assessing pre- and post-market clinical and non-clinical safety and effectiveness issues for CNS-related drugs. She also served on the United States Pharmacopeia Neurology Expert Committee (2000-2005). Dr Lim has received several awards, including for Excellence in Risk Management and for Creativity and Innovation. Her interests also include best review community practices, patient-focused regulation and life-cycle evidence generation systems. Since 2007, she has participated and presented at international endeavors developing benefit-risk and uncertainty science. She has been a member of the MIT NEWDIGS AL team since 2011. Dr Lim also works with Canadian patients, creating a patient's treatment benefit-harm-uncertainty decision guide. Dr. Lim received Bachelor and Master's degrees in biochemistry from Queen's University at Kingston, Ontario, Canada and a Doctorate in molecular neurophysiology from the Physiological Laboratory, University of Cambridge, U.K. and Trinity College, Cambridge, U.K

**Laura Maliszewski, PhD**
Executive Director, Harvard Program in Therapeutic Science (HiTS)
HMS Laboratory of Systems Pharmacology (LSP)
Harvard Medical School

Dr. Maliszewski joined HMS in September 2012 to establish the Laboratory of Systems Pharmacology and the Harvard Program in Therapeutic Science. She oversees the research, education and outreach activities of the HiTS program which combines computational modeling and precise measurement to understand drug action in humans. HiTS research takes place in ~10,000 ft2 of laboratory space open to the Boston research community. Prior to returning to HMS, Maliszewski was an Officer in the Science and Innovation Network of the UK Foreign and Commonwealth

Office, developing a broad portfolio of research collaborations in regenerative medicine, health economics and stratified medicine. She is responsible for the strategic alliance of the UK Stem Cell Bank with the Massachusetts Human Stem Cell Bank and Registry, and contributed to the development of the UK Catapult Centers for technology development.

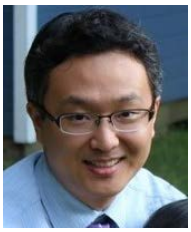
Laura holds a BS in Biotechnology from the University of Delaware and a PhD in Virology from the Harvard Division of Medical Sciences. She completed her doctoral studies in the lab of Judy Lieberman at the Immune Disease Institute and Harvard Medical School studying the perturbation of microRNAs during HIV infection of primary lymphocytes.

**Erica Marshall, MPH**
Director, Asthma Prevention and Control Program (APCP)
Division of Prevention and Wellness
Massachusetts Department of Public Health

Erica Marshall, MPH, is the Director of the Asthma Prevention and Control Program (APCP) at the Massachusetts Department of Public Health. She leads the APCP in achieving its mission, focusing on building supportive infrastructure for CHW-led asthma home visiting in Massachusetts, including training and technical assistance, developing the evidence-base for these interventions, and working to promote broad adoption and payment for such services. Ms. Marshall joined the Massachusetts Department of Public Health in 2010 as the Reducing Ethnic/Racial Asthma Disparities in Youth (READY) study coordinator and assumed the role of Asthma Director in summer 2013. Ms. Marshall leads the APCP in achieving its mission to improve the quality of life for all Commonwealth residents with asthma and to reduce disparities in asthma outcomes.

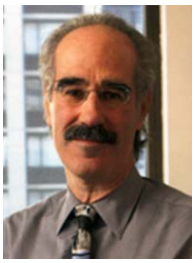
**Jennifer E. Miller, PhD**
Assistant Professor, Yale School of Medicine
Founder, Bioethics International

Jennifer E. Miller, PhD, is an Assistant Professor at Yale University School of Medicine and Founder of *Bioethics International*, a nonprofit dedicated to raising the bar on bioethics and patient-centricity in the pharmaceutical sector. She also founded the *Good Pharma Scorecard*, an index that ranks new drugs and pharmaceutical companies on ethics and patient-centricity performance criteria, and is a member of The World Economic Forum. Dr. Miller's work explores the ethics and governance of how medicines, biologics, and health technologies are researched, developed, marketed, priced, and made accessible to patients, as well as the ethics of big data, AI and machine learning in healthcare. Prior to joining Yale's faculty, she was based at NYU School of Medicine, Duke University, and Harvard University.



**Kevin K. Nam, PhD**
Research Staff
MIT Lincoln Laboratory

Dr. Kevin Nam is a research staff and project manager at MIT Lincoln Laboratory in Lexington, Massachusetts, where he is responsible for managing projects and teams to develop software prototypes and user focused technologies to support various internal and external research efforts. His research interests include collaborative system architecture, research data management, software engineering, information visualization, and wearable systems. He has a B.S. in Computer Science from University of Texas, Dallas, M.S. in Computer Science and Ph.D. in Information Science from University of Michigan where he investigated user behaviors and knowledge transfer patterns in an extremely large online question-answer community, and developed a prototype software that would enable knowledge distillation of a large, informal discussion space through visualization and natural language processing to facilitate quality knowledge creation.



**David M. Nathan, MD**
Director
Diabetes Center and Clinical Research Center
Massachusetts General Hospital

David M. Nathan, MD, is a professor of Medicine at Harvard Medical School and director of the Clinical Research Center and Diabetes Center at Massachusetts General Hospital. His major research focus is the study and development of new methods to normalize glucose metabolism in diabetes mellitus and the long-term consequences of such therapy. He was one of the architects of the Diabetes Control and Complications Trial and currently co-chairs its long-term follow-up, the Epidemiology of Diabetes Interventions and Complications Study. He is the chairman of the multi-center NIH Diabetes Prevention Program and the GRADE Comparative Effectiveness Study of Type 2 Diabetes. Dr. Nathan has

chaired the International Expert Committee on the diagnosis of diabetes and the International Consensus Committee on the treatment of type 2 diabetes. Having authored more than 500 publications, chapters and books, Dr. Nathan is an internationally recognized expert on diabetes and its treatment and complications. He was awarded the Outstanding Clinician Award by the American Diabetes Association in 2002 and the National Institute of Diabetes Digestive and Kidney Disease Distinguished Scientist Award in 2010.

**Kelly Necastro, MPH**
Project Coordinator, LEAPS
Center for Biomedical Innovation: NEWDIGS
Massachusetts Institute of Technology

Kelly Necastro is the LEAPS Project Coordinator for the NEWDIGS Initiative at the MIT Center for Biomedical Innovation. Prior to joining MIT, Kelly spent several years working in clinical and sociobehavioral research project management in both academic medical center and community health center settings on such topics as substance use and obesity in pregnancy and early child development. Kelly earned her BS from the University of Illinois at Urbana-Champaign and MPH from the Boston University School of Public Health.

**Megan O'Brien, PhD**
Executive Director
Center for Observational and Real World Evidence
Merck & Co., Inc.

Megan O'Brien, PhD, MPH leads the Medical Policy and Quality Research group within the Center for Observational and Real World Evidence at Merck. In this role, Megan leads a team of researchers who conduct quality and policy related studies relevant to Merck products. Megan has been with Merck for 10 years, and her previous roles involved value evidence research for vaccines and health economic modeling for various product areas. Megan received a PhD from the Johns Hopkins Bloomberg School of Public health and a Masters Degree in Public Health from Emory University.

**Jennifer K. Pai, ScD**
Director
Data Sciences, Strategy, and Platforms
Merck & Co., Inc.

Jennifer K. Pai, ScD is currently the Director of Data Sciences, Strategy, and Platforms at Merck & Co., Inc focused on advancing translational applications of data sciences and predictive analytics to accelerate the development of observational and real world evidence research. Previous to this role, Dr. Pai held leadership roles in the IT organization as the health informatics and data strategy lead focused broadly on enabling data interoperability, increased data utility, and analytics across the drug discovery pipeline. Prior to joining Merck, Dr. Pai was on the faculty at Harvard Medical School where she led an independent research program evaluating novel plasma and genetic biomarkers as risk predictors of cardiovascular disease. Dr. Pai has coauthored >45 publications in leading journals and served as expert reviewer for journals, scientific conferences, and national funding agencies. She holds degrees from The Johns Hopkins University and a Doctorate degree in Epidemiology from Harvard University.

**Melissa Paoloni, MA, DVM, DAVIM-O**
Director
Clinical Trial Science
Berry Consultants, LLC

Melissa Paoloni is a Director of Clinical Trial Science for Berry Consultant's Clinical Trial Strategy Team, whose mission is to accelerate the clinical development process by designing and implementing innovative, adaptive, and platform trials across all therapeutic areas. Dr. Paoloni's expertise is in innovative clinical trial design in all phases of drug development (preclinical-phase 3) and platform and adaptive trial implementation. She has specific phase 1 proficiency, a medical oncology background, genomics and molecular oncology knowledge, intellectual property understanding, and strong business development and relationship building skills.

Dr. Paoloni received her Doctor of Veterinary Medicine at Tufts University, completed her residency in Medical Oncology at the University of Wisconsin-Madison, and received her Masters degree in Clinical Trial Design from Duke University. She then joined the National Cancer Institute for her post-doctoral fellowship prior to moving into a Staff Scientist position. While at the NCI for 9 years, she ran a pre-clinical modeling group focused on oncology drug development that worked with many academic, pharmaceutical and biotech partners. In 2013

she joined QuantumLeap Healthcare Collaborative as the Executive Director of Clinical Activities for the I-SPY Program. Dr. Paoloni facilitated partnerships with pharmaceutical companies, regulatory agencies, and institutions for the I-SPY 2 TRIAL, a phase 2 trial to evaluate novel drugs in the neoadjuvant setting for women with high-risk breast cancer. She was also involved in the expansion of the I-SPY Program with the development and execution of the I-SPY phase 1 network and the design of the I-SPY 3 TRIAL. Currently she and her team are overseeing the build of the GBM AGILE and Precision Promise trials. She has been an invited speaker to many academic and industry groups on accelerating drug development and the benefits of translational research.

**Lauren B. Peters, JD**
Undersecretary for Health Policy
Deputy General Counsel & Director of Healthcare Policy & Legislative Affairs
Massachusetts Executive Office of Health and Human Services

Lauren Peters is the Undersecretary for Health Policy at the Executive Office of Health and Human Services (EOHHS), the largest secretariat in the Commonwealth. Peters' responsibilities include working closely on health-related operations and policy for the MassHealth (Medicaid) program that provides health coverage to 1.9 million low income or disabled residents; the Department of Mental Health; and the Department of Public Health. Peters also works closely with EOHHS boards and commissions such as the Massachusetts Health Connector and the Center for Health Information and Analysis Oversight Council. Prior to joining EOHHS, Peters served as Associate General Counsel, Health Care Policy Director, and Legislative Director at the Executive Office for Administration and Finance (A&F) where she served as an advisor on healthcare finance and policy matters. In that role, Peters also served as the A&F Secretary's designees on several boards and commissions including the Health Policy Commission, Group Insurance Commission and the Health Information Technology Council. She has a law degree from Suffolk University Law School and a bachelor's degree from Hobart and William Smith Colleges.

**Richard Polisson, MD, MHSc**
SVP & Head, Translation Medicine (retired)
Research and Development Center
Sanofi-Genzyme

Richard P. Polisson, MD, MHSc was Senior Vice President (Genzyme) and Head of Translational Medicine at Sanofi-Genzyme Research and Development Center (SGRDC), Cambridge and Framingham, MA. In this role he was responsible for managing and aligning the SGRDC TM research physicians with projects at the earliest stages of discovery research and directing the review and endorsement of all the TM plans (eg. disease indication selection, target credentialing, biomarker plan, "Proof of Concept" studies, and early human trials) across the therapeutic areas of Rare/Genetic Diseases, Multiple Sclerosis/Neurology, Immune-Mediated Diseases, and Fibrosis and Tissue Repair. He was a core member of the Sanofi North American Hub Research Council and the global Sanofi External Working Group.

Dr. Polisson came to the pharmaceutical industry 20 years ago from Massachusetts General Hospital (MGH) and Harvard Medical School (HMS), where he was Associate Professor of Medicine, Clinical Director of the Arthritis Unit, and Chair of the Mallinckrodt Clinical Research Unit Scientific Advisory Committee. Dr. Polisson has formal Master's level training in the quantitative methods of clinical investigation, and has 30 years of experience in clinical and translational research, beginning initially at the National Cancer Institute/NIH, and subsequently in academia (Duke, MGH/HMS). He received his BS from Yale University and his MD from Duke University School of Medicine. He is the author of more than 120 manuscripts, chapters, and abstracts.

**Judith Reece, PhD, MB, MBA, FRCBiol**
Vice President
Digital Development
GlaxoSmithKline

D.r Judith Reece is VP Digital Development at GSK and is based out of London, United Kingdom, where she is responsible for a team tasked with using agile methodologies that leverage Digital data and analytic approaches to transform how GSK develops medicines taking a customer centric approach. Dr. Reece joined GSK 18 months ago previously working at AstraZeneca for 15 years where she worked in a variety of roles in R&D and at the Corporate level leading drug projects, change programmes and was a leader in the Corporate Strategy and Development team. Prior to joining the Pharmaceutical industry Dr Reece worked in Academia in the UK and in the US, where her research intersts focused on the interface between clinical research and medical practice.

**Monica Ruse, PhD**
Program Director
Harvard-MIT Center for Regulatory Science
Harvard Medical School

Dr. Monica Ruse is the Program Director for the Harvard-MIT Center for Regulatory Science, where she is responsible for the implementation of Center activities including the Regulatory Science fellowship program, management of collaborative research activities with faculty and stakeholders and financial administration of the center. Prior to joining Harvard as a senior grants manager in 2014, Monica led the administration of grants and biomedical projects at the Division of Reproductive Health of Population Council, an international non-profit NGO headquartered in New York. She holds a Ph.D. in Cell Physiology from Case Western Medical School and a Bachelor of Science in Physics from University of Bucharest.

**Monica Sawhney, MPH**
Deputy Chief of Staff, MassHealth
Massachusetts Executive Office of Health and Human Services

Monica Sawhney is the Deputy Chief of Staff for MassHealth, the Commonwealth's Medicaid agency. She was previously the Policy Manager at the Massachusetts Health Safety Net Office. Prior to working for the state, Monica worked at Steward Health Care, focusing on clinical integration and care management initiatives. She also spent a number of years in the non-profit sector, working with Health Leads, an organization that strives to bridge the gap between health care and social services. Monica is a graduate of Boston University and the Boston University School of Public Health.

**Debra A. Schaumberg, ScD, OD, MPH**
Vice President
Scientific Affairs &, Real-World Evidence
Evidera | PPD

Debra is an internationally recognized expert in ophthalmology and epidemiology and brings more than 20 years' experience designing and leading research investigations spanning the spectrum of RCT through all aspects of real-world evidence (RWE) generation and integration. Debra works externally with clients, industry, and academic contacts, and internally across the PPD organization, to advance scientific aspects of established individual service offerings as well as to contribute to the conceptualization, delivery, and commercialization of new/emerging RWE multi-method client solutions. Debra has worked in early stage clinical development through medical affairs and life-cycle management roles. She has authored hundreds of scientific publications, lectures, and scientific presentations. She has held leadership roles in academia including Harvard Medical School, the Harvard TH Chan School of Public Health, and the University of Utah School of Medicine; in biopharma including as Global Medical Director for Ophthalmics and then as Head of Medical Evidence at Shire, and diverse experience with biotherapeutic start-ups and venture capital teams. Debra received her ScD from the Harvard TH Chan School of Public Health, an MPH from the Johns Hopkins Bloomberg School of Hygiene and Public Health, research fellowship at the Johns Hopkins School of Medicine, and an OD summa cum laude from the Illinois College of Optometry.

**Amy Schultz**
Associate Director
Finsbury

Amy Schultz is an Associate Director at Finsbury, a global strategic communications consultancy, where she specializes in reputation management for leading global companies and nonprofits. Prior to joining Finsbury, Amy worked in the corporate philanthropy group at Toyota Motor North America. She graduated magna cum laude from Columbia University with a B.A. in Anthropology and explored her interest in Human-Centered Design through IDEO.org's "Design Kit" certification. Amy lives in Brooklyn, NY. She was diagnosed with Type 1 Diabetes in 2003.

**Diane M. Simeone, MD**
Professor of Surgery and Pathology, NYU Langone Medical Center
Associate Director of Translational Oncology Program, Perlmutter Cancer Center
Director, Pancreatic Cancer Center, NYU Langone Medical Center

Diane Simeone is the Laura and Isaac Perlmutter Professor of Surgery and Pathology at New York University and the Director of the Pancreatic Cancer Center at NYU Langone Health. She also serves as the Associate Director for Translational Research for the Perlmutter Cancer Center at NYU. She has been the recipient of numerous NIH grants (multiple R01s, U01, P50) investigating the molecular mechanisms driving pancreatic metastasis and the development of novel, more effective therapeutic strategies to treat pancreatic cancer patients. She also runs a large, multi-institutional research program focused on developing an early detection blood test for pancreatic cancer. She has served as President of both the Society of University Surgeons and the American Pancreatic Association. Dr. Simeone is currently the Chair of the National Scientific and Medical Advisory Board for the Pancreatic Cancer Action Network (PanCAN) and serves as the Principal Investigator on the Precision Promise Project, focused on developing a new national pancreatic cancer clinical trial infrastructure. She has served on the Board of Directors for the National Pancreas Foundation and on the Lustgarten Foundation Scientific Advisory Board, and is currently on the NCI Pancreatic Cancer Task Force and Early Detection Working Group. She is the recipient of the Randy Pausch Family Innovation Award (AACR) and the Nina Braunwald Distinguished Professor Award (Harvard University). Dr. Simeone is a member of the National Academy of Medicine.

**Stacy L. Springs, PhD**
Senior Director of Programs, MIT Center for Biomedical Innovation; Executive Director, Biomanufacturing Program (BioMAN) & Consortium of Adventitious Agent Contamination in Biomanufacturing (CAACB)
Massachusetts Institute of Technology

Dr. Stacy Springs is the Senior Director of Programs for the MIT Center for Biomedical Innovation (CBI), the Executive Director of CBI's Biomanufacturing Program (BioMAN) and Consortium of Adventitious Agent Contamination in Biomanufacturing (CAACB). BioMAN is a collaborative research and educational program in biotherapeutic manufacturing that involves biopharmaceutical manufacturers, vendors, regulators, other government stakeholders, and academics. The Objective of this program is to develop new knowledge, science, technologies, and strategies for advancing the safe manufacture and global delivery of high-quality biopharmaceuticals. The CAACB was established to share information around adventitious agent contamination and risk mitigation for the benefit of biopharmaceutical manufacturing industry and the patients receiving medication produced from cell culture.

Dr. Springs recently served as the Associate Director of the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), whose mission is to accelerate biopharmaceutical manufacturing innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce, fundamentally advancing U.S. competitiveness in this industry.

Dr. Springs holds a PhD in Chemistry from the University of Texas at Austin and gained postdoctoral training in protein and biophysical chemistry at Princeton University. Prior to joining MIT, Stacy was a Senior Scientist and Director of Collaborative Projects at Tetralogic Pharmaceuticals, an oncology drug discovery company based in Malvern, PA.

**Daniel Staud, MBA**
AVP, Global Market Access Strategy
Merck & Co., Inc.

Dan Staud is the AVP of Global Access Strategy at Merck. The Global Access team is responsible for leading the development and operational implementation of market access strategies for company in-line and pipeline products covering vaccines, hospital acute care and chronic care franchise areas. Value communication tools, stakeholder assessments and negotiations plans delivered to the organization ensure broad understanding of the strategy and any associated reimbursement risks that may create potential implications to commercial forecasts and viability.

Prior to joining Merck, Dan held market access and pricing leadership roles at Regeneron Pharmaceuticals, GSK and Wyeth Pharmaceuticals inclusive of a pharmaceutical industry career of over 25 years.

Dan holds a B.S. from Fairleigh Dickinson University and an MBA from St. Joseph's University.

**David R. Strutton, PhD**
Vice President of Global Pharmaceuticals and Policy Research
Center for Observational and Real-World Evidence
Merck & Co., Inc.

David R Strutton, PhD, MPH is Vice President of Global Pharmaceuticals and Policy Research in the Center for Observational and Real-World Evidence (CORE) at Merck. He has global responsibility for developing integrated value evidence strategies, as well as for generating evidence to support policy objectives regarding health technology assessment (HTA), pricing and reimbursement, healthcare system inefficiencies, affordability and health care quality. Prior to joining Merck, David worked as a consultant to the pharmaceutical industry and lead Pfizer's Vaccines Global Health and Value team, where he was responsible demonstrating the public health and economic value of Pfizer's vaccines, as well as for global market access and pricing strategies to establish and sustain reimbursement for national immunization programs throughout the world. David received his PhD in Health Economics from the Johns Hopkins University Bloomberg School of Public Health, where he has had a faculty appointment since 2005.

**Secretary Marylou Sudders, MSW**
Secretary of Health and Human Services
Massachusetts Executive Office of Health and Human Services

Marylou Sudders serves as Massachusetts' Secretary of the Executive Office of Health & Human Services (EOHHS) the largest executive agency in state government directly touching the lives of 1 in 4 residents. Secretary Sudders oversees a $23 billion state budget; 22,000 public servants; twelve agencies; and the MassHealth (Medicaid) insurance program that provides health coverage to 1.86 million low income or disabled residents. She also leads the Commonwealth's efforts to address the opioid epidemic; chairs the state's health care marketplace (The Connector); the Autism Commission; co-chairs the Governor's Interagency Council on Homelessness and the state's first Governor's Council to Address Aging in Massachusetts.

Professionally trained as a social worker, Secretary Sudders has been a public official, private non-profit executive, advocate and college professor. She served as the Massachusetts Commissioner of Mental Health from 1996 to 2003 and has been recognized by top business, social work and civic organizations, including the Boston Chamber of Commerce, Massachusetts Taxpayers Foundation, Eastern Bank, and the National Association of Social Work.

Sudders, is an alumna of Boston University with a Bachelor's degree with honors and a Master's degree in social work, and has received an honorary doctorate from the Massachusetts School of Professional Psychology.

**David Tester, PhD, MS**
Head of Data Science and Engineering
Chief Data Office
Sanofi

Dr. David Tester is the Head of Data Science and Engineering at Sanofi - where his team solves complex "big data" and machine learning problems across all segments of the company. David was previously at Google/Verily where he led or contributed to several projects including causal modeling of clinical data and projects in cloud-based genomics in collaboration with the Broad Institute of Harvard/MIT. Prior to Google he worked at the Novartis Institute for Biomedical Research on various projects in genomics-based drug discovery. David holds degrees from the University of Illinois, Oxford University, Johns Hopkins University, and is based in Cambridge, MA.

**Dapo Tomori, MD, MBA**
Strategic Innovation Leader
Genentech

Dapo's career integrates broad experiences across clinical Medicine, academia, biopharma and healthcare systems and services. He currently works at Genentech, where he leads strategic innovation initiatives in product development.

He has worked in leadership roles in strategy, product development and innovation at Eli Lilly and Company, Takeda Pharmaceuticals and Anthem. He previously held faculty appointments at the University of Michigan School of Medicine and the University of New Mexico. He remains an adjunct faculty member at the University of New Mexico School of Medicine.

He trained in psychiatry at the University of Michigan and obtained his medical degree from the University of Ibadan, in Nigeria. He received an MBA degree from the Massachusetts Institute of Technology, Sloan School of Management and studied International Health Policy at The London School of Economics.

He currently serves on the National Advisory Board at the University of Michigan Depression Center.

**Mark Trusheim, MS**
Strategic Director, NEWDIGS
Visiting Scientist, Sloan School of Management
Massachusetts Institute of Technology

Mark Trusheim is a Visiting Scientist and Executive-In-Residence at the MIT Sloan School of Management. He has been a Special Government Employee for the FDA's Office of the Commissioner and is the Founder and President of Co-Bio Consulting, LLC. He holds degrees in Chemistry from Stanford University and Management from MIT. His research focuses on the economics of stratified (personalized) medicines, particularly the integrated quantitative modeling of stratified medicine development and commercialization, to inform public policy, corporate strategy and individual product development programs. Together with the FDA and industry, he led a multi-disciplinary consortium to examine the economic challenges of co-development of companion diagnostics and therapeutics whose work was covered by the Nature Review Drug Discovery. In addition, he has been a frequent invited speaker on stratified medicine at international conferences and conducts confidential workshops and analyses for biopharmaceutical and diagnostic firms. Prior to his work in stratified medicine, he was a Board Member and Interim President of the Massachusetts Biotechnology Council. As an entrepreneur, he founded and was the first President and CEO of Cantata Laboratories which developed and marketed biochemical profiling clinical diagnostics and pharmaceutical biomarker services. Prior to Cantata, he worked at Monsanto/Pharmacia, culminating his career there as Co-President and Chief Operating Officer of Cereon Genomics, LLC-a 5 year, $500M collaboration with Millennium Pharmaceuticals, and held roles of Vice President in the Health & Wellness Sector, Marketing Director in Searle Pharmaceutical and Director in Agriculture Division Strategy. He spent the first half of his career in the high tech industry at both Wang Laboratories in computer hardware and the start-up Kenan Systems Corporation which focused on developing quantitative models and artificial intelligence based applications for large corporations and government agencies.

**Pranay Udutha**
Dean's Scholar, Milken Institute of Public Health
George Washington University

Originally from Ruston, Louisiana, Pranay graduated with degrees in International Affairs & Biology from the University of Georgia. His professional experience began in research spanning three continents, in regenerative medicine and pharmaceutical science. In the public policy realm, he previously completed a fellowship at the American Enterprise Institute and served with a Congressman from Georgia, Rob Woodall. He served in the office of Senator Bill Cassidy, M.D. since the end of 2014 and was a Policy Advisor working on tax/finance/budget issues, pharmaceutical policy, and health reform efforts. He is currently working on his master's degree in public health at George Washington University, focusing on health policy and management.

**Thomas F. Unger, PhD, MBA**
Co-founder and Chief Strategy Officer
Naia Pharmaceuticals Ltd.

Dr. Unger is co-founder and Chief Strategy Officer of Naia Pharmaceuticals Ltd, a company that develops therapeutics through innovative models and collaborative partnerships with governments, agencies and strategic partners to address the concerns and objectives of emerging and major markets. Prior to Naia, Dr. Unger held a number of senior positions at Pfizer Inc. including within the Development Operations and Worldwide Regulatory Strategy organizations. He was the Head of Strategy for Pfizer's Biotherapeutics and Bioinnovation Center (BBC) where he was responsible for all strategic, organizational and capital planning initiatives for the division. He joined Pfizer as a Senior Director in the Strategic Management Group within Pfizer Global Research and Development (PGRD) where he was a member of the Development Leadership Team and responsible for leading strategic and operational initiatives within the R&D organization.

While at Pfizer, Dr. Unger was responsible for initiating a number collaborative innovation initiatives, including that as a co-founding member of MIT/NEWDIGS. He currently serves on the Advisory Boards of a number of emerging biotech companies and foundations.

Before joining Pfizer, he held a number of senior strategic advisory positions including the investment banking firms Aperion Partners, LLC and MTM Advisors, LLC, and the management consulting firms Wood Mackenzie Limited and PA Consulting Group. He started his

industry career as co-founder of a number of early stage biotechnology companies including BioLogic Technologies and Miragen Incorporated.

Dr. Unger obtained his BS in Biology from the University of Southern California, his PhD in Biological Sciences from the California College of Medicine, University of California, Irvine and his MBA from the Marshall School of Business, University of Southern California.

**Ed Wack, MS**
Assistant Division Head
Homeland Protection
MIT Lincoln Laboratory

Edward C. Wack is the Assistant Head of the Homeland Protection and Air Traffic Control Division at MIT Lincoln Laboratory. In this role, he shares responsibility for research, development, evaluation, and technology transfer of advanced technologies and systems for chemical and biological defense, bioengineering, and biomedical systems. Prior to this position, Mr. Wack was the Leader of the Bioengineering Systems and Technologies Group, which focuses on innovative advanced technology programs in biodefense, forensics, and biomedical research. The group's broad technical areas include bioinformatics, integrative genomics, synthetic biology, physiological and cognitive monitoring, and advanced signal processing.

Mr. Wack was also the Director of Future Acquisition at the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) within the Department of Defense. He was responsible for leading the JPEO-CBD's future technology strategy and coordinating that strategy with the other members of the chemical and biological defense program, civilian government organizations, and international partners. He led efforts to develop integrated system of systems concepts for chemical and biological defense.

Before joining the JPEO-CBD, Mr. Wack spent 13 years at Lincoln Laboratory. He was an Assistant Leader of the Sensor Systems and Applications Group, where he led a team working on standoff sensing, advanced detection algorithms, and system architectures. He has also been involved in various aspects of satellite remote sensing programs, including system architectures, sensor designs, sensor calibration, and requirements analysis and definition.

Mr. Wack earned a BA degree in mathematics from the College of the Holy Cross and an MS degree in bioinformatics from Brandeis University.

**Teresa Wilcox, PhD**
Vice President
Real-World Evidence
Evidera | PPD

Teresa (Terry) Wilcox, PhD**,** is a Vice President, Real-World Evidence at Evidera. In her role, Dr. Wilcox provides strategic consultation regarding evidence planning and generation to address stakeholder needs for market access. Additionally, she participates in the design, analysis, and interpretation of global studies in health economics and outcomes research (HEOR) with a specific focus on research questions requiring real-world evidence (e.g., disease burden, patient journey [including treatment patterns], impact of diagnostics, preventatives, or interventions, as well as linking clinical trial results to clinical practice). She has experience in a variety of study designs (chart reviews, registries, pragmatic trials) and therapeutic areas including Alzheimer's disease, immunology, migraine, oncology, and pain, and has done extensive work in respiratory conditions.

Dr. Wilcox worked as a pharmacist for 10 years with responsibilities for Drug Usage Evaluation, Adverse Drug Event monitoring, formulary assessment, and investigational drug service. Investigational drug studies included national cooperative trials in oncology, cardiology, and infectious disease. Additionally, she served as a voting member of the local institutional review board (IRB). Her experience in industry includes working for GlaxoSmithKline for 12 years where she initially was part of the international pharmacoeconomic group located in London. Subsequently, Dr. Wilcox was a senior regional medical scientist where she provided medical information to clinicians and payers, discussed and developed disease management guidelines/algorithms, and served as a link to research and development initiatives.

Dr. Wilcox is widely published in peer-reviewed journals and has presented her work at major professional clinical conferences. Additionally, she has been an invited lecturer on topics in her field at such institutions as the University of California San Diego, The Ohio State University, Ohio Northern University, and the University of Maryland. Dr. Wilcox is a member of many professional societies, including the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), Academy of Managed Care Pharmacy (AMCP), and the American Thoracic Society (ATS). Dr. Wilcox completed her PhD from The Ohio State University with an emphasis in health outcomes and epidemiology.

**Susan R. Windham-Bannister, PhD**
President & CEO
Biomedical Growth Strategies, LLC

Dr. Susan Windham-Bannister is a nationally and internationally recognized expert in biopharma innovation, market access and market optimization strategies. She has been recognized by the Boston Globe as one of the "10 Most Influential Women in Biotech," by Boston Magazine as one of the "50 Most Powerful Women in Boston" and is the incoming President of the National Board of Directors of the Association for Women in Science (AWIS). Dr. Windham-Bannister President and CEO of Biomedical Growth Strategies, LLC.

From 2008-2015 Dr. Windham-Bannister served as President and CEO of the Massachusetts Life Sciences Center (MLSC), an independent authority charged with administering a $1-billion Life Sciences investment fund created by Governor Deval Patrick. She is the first African American in the U.S. to lead a life sciences-focused innovation fund of this scale. The MLSC invests to catalyze innovation in all sectors of the Massachusetts life sciences community – biotechnology, pharmaceuticals, medical devices, medical diagnostics and bioinformatics/analytics. Since completing her tenure as President and CEO of the Massachusetts Life Sciences Initiative, Dr. Windham-Bannister has been an advisor to other city, state and regional life sciences initiatives in the U.S. and abroad.

Dr. Windham-Bannister received a B.A. from Wellesley College, a Doctorate in Health Policy and Management from the Florence Heller School at Brandeis University, and a Doctor of Science from Worcester Polytechnic Institute (honoris causa). She completed her doctoral work at the Heller School under a fellowship from the Ford Foundation and was also a post-doctoral fellow at Harvard University's John F. Kennedy School. Dr. Windham-Bannister also served as a Fellow in the Center for Science and Policy (CSAP) at Cambridge University, Cambridge, England.

**Helen Yang**
Program Manager
Harvard-MIT Center for Regulatory Science
Harvard Medical School

Helen Yang is the Program Manager of the Harvard-MIT Center for Regulatory Science (CRS), which supports the advancement of regulatory science research and applications to enable better, faster, and more effective routes for developing new therapeutics. Prior to joining CRS, Helen helped launch multiple biotech startups, contributing in business strategy, operations, and marketing. She was most recently part of the founding team of PercepTx, an oncology startup developing novel antibody drug conjugates using its proprietary, high-throughput biologics discovery and development platform. Helen is passionate about enabling better therapeutic innovations for patients in need and has a Bachelor of Science degree in Materials Science and Engineering from MIT.

**Sachin Yende, MD, MS**
Vice President
Critical Care
Veterans Affairs Pittsburgh

Dr. Sachin Yende is Vice President of Critical Care at Veterans Affairs hospital, Pittsburgh and Professor of Critical Care at the University of Pittsburgh. His research interests include sepsis and pneumonia, particularly designing precision medicine approaches for sepsis.

**Deborah Young, MBA**
Director of Operations, NEWDIGS
Center for Biomedical Innovation
Massachusetts Institute of Technology

Deborah Young joined the NEWDIGS team in February of 2016, having spent 3 years working at MIT on MVISION, a joint partnership with the Madrid government in a program management role. Prior experience includes managing operations at a senior level for a premiere international broadcast organization based in both Singapore and London, with responsibility for Asia and UK/Europe respectively. She has an MBA from the State University of New York and a Masters in Higher Education Administration from Boston University.

**Qi Zhou**
Vice President
Performance Analytics and Quality Management
Blue Cross Blue Shield of Massachusetts

Qi Zhou leads a cross-functional team responsible for development of performance measurement and strategy that are central to pay-for-performance, public reporting, quality-related product design, payment reform, clinical outcomes, disparity care, quality and patient safety improvement. Qi oversees consumer data governance and consumer analytics in supporting Enterprise Analytics and Consumer Engagement strategies. He is also responsible for assessing data sources and governance to enhance enterprise analytics capability including clinical data from EMRs, patient reported outcomes, and third parties consumer data.

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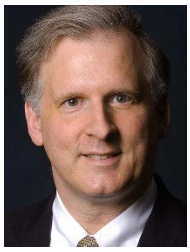
## ABSENT, WITH APOLOGIES:

**Anna D. Barker, PhD**
Co-Director, Complex Adaptive Systems (CAS)
Director, National Biomarker Development Alliance (NBDA)
Professor, School of Life Sciences
Arizona State University (ASU)

CAS at ASU creates knowledge networks to solve complex systems problems in biomedicine. Examples of current programs include the NBDA, a non-profit think tank that addresses major barriers in biomarker discovery and development, and the first global adaptive clinical trial for glioblastoma (GBM AGILE). Prior to ASU, Dr. Barker served as the deputy director of the National Cancer Institute(NCI) where she planned and implemented the: Nanotechnology Alliance for Cancer; The Cancer Genome Atlas (TCGA) with NHGRI; Clinical Proteomics Technologies Initiative for Cancer; Physical Sciences-Oncology Centers; and national programs in biospecimens and bioinformatics. Prior to NCI, Dr. Barker served as a research scientist and subsequently senior executive at Battelle Memorial Institute and as the CEO of a public biotechnology company. She has received a number of awards for her work and service. Her research interests include CAS, biomarker discovery and development, innovative clinical trials and free-radical biochemistry. She completed her Ph.D. degree at The Ohio State University.



**Gerald J. Dal Pan, MD, MHS**
Director, Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research
FDA

Gerald J. Dal Pan, MD, MHS currently serves as the Director of the Office of Surveillance and Epidemiology in FDA's Center for Drug Evaluation and Research, where since 2005 he has been responsible for the Center's programs in adverse event surveillance and analysis, pharmacoepidemiology, risk management, and medication error prevention. In this capacity, he is involved in both the premarket and postmarket regulation of drugs and therapeutic biologics, and in the implementation of the drug safety provisions of the Food and Drug Administration Amendments Act and other initiatives. He is a member of the World Health Organization Advisory Committee on the Safety of Medicinal Products, and has served on working groups of the Council of International Organization of Medical Sciences (CIOMS) and the International Conference on Harmonisation (ICH). He received his MD at Columbia University College of Physicians and Surgeons and his Master of Health Science in Clinical Epidemiology at the Johns Hopkins University School of Hygiene and Public Health. He completed residency training in Internal Medicine at the Hospital of the University of Pennsylvania and in Neurology at the Johns Hopkins Hospital. He is board certified in both Internal Medicine and Neurology. He joined FDA in 2000 as a medical reviewer in the Center's Office of New Drugs. Before working at FDA, he was a faculty member in the Department of Neurology at Johns Hopkins and worked in the pharmaceutical industry.

**Elazer R. Edelman, MD, PhD**
Director, Institute for Medical Engineering and Science (IMES),
Department Head, Thomas D. and Virginia W. Cabot Professor, Health Sciences and Technology
Massachusetts Institute of Technology

Elazer R. Edelman, M.D., Ph.D., is the Thomas D. and Virginia W. Cabot Professor of Health Sciences and Technology at MIT, Professor of Medicine at Harvard Medical School, and Senior Attending Physician in the coronary care unit at the Brigham and Women's Hospital in Boston. He and his laboratory have pioneered basic findings in vascular biology and the development and assessment of biotechnology. Dr. Edelman directs the Harvard-MIT Biomedical Engineering Center (BMEC), dedicated to applying the rigors of the physical sciences to elucidate fundamental biologic processes and mechanisms of disease.

Dr. Edelman received Bachelor of Science degrees in Bioelectrical Engineering and in Applied Biology from MIT, a Master of Science degree in Electrical Engineering and Computer Sciences from MIT, a Ph.D. in Medical Engineering and Medical Physics from MIT, and an M.D. degree from Harvard Medical School. His graduate thesis work, under the direction of Prof. Robert Langer, defined the mathematics of regulated and controlled drug delivery systems. After internal medicine training and clinical fellowship in Cardiovascular Medicine at the BWH he spent six years as a research fellow in the Department of Pathology at Harvard Medical School with Prof. Morris J. Karnovsky working on the biology of vascular repair.

Dr. Edelman is a fellow of the American College of Cardiology, the American Heart Association, the Association of University Cardiologists, the American Society of Clinical Investigation, American Institute of Medical and Biological Engineering, the American Academy of Arts and Sciences, National Academy of Inventors, the Institute of Medicine/National Academy of Medicine, and the National Academy of Engineering. As Chief Scientific Advisor of Science: Translational Medicine he has set the tone for the national debate on translational research and innovation. As co-founder of ASTM F04.03 he helped create standards for cardiovascular implants. He served as a member of FDA's Science Board and an ORISE fellow in the FDA EIR. For his work bringing cardiovascular translational research to an international level of excellence, the Spanish Parliament and King Juan Carlos awarded Dr. Edelman with the Spanish Order of Civil Merit for his work. Most importantly, Elazer is an avid ice hockey goalie, and with his wife Cheryl are parents to comedian and writer Alexander, Olympic athlete AJ, and Austin.

**Anne-Virginie Eggimann, MSc**
Vice President, Regulatory Science
bluebird bio, Inc.

Anne-Virginie Eggimann joined bluebird bio in September 2011 to lead the Regulatory Science function. In her role as Vice President, she is responsible for global regulatory strategy and is focused on finding innovative pathways to accelerate the development of bluebird bio's gene therapy products to meet significant unmet medical needs in debilitating and life-threatening conditions. Prior to joining bluebird bio, Ms. Eggimann was an Executive Director at Voisin Consulting Life Sciences, leading projects involving the design and implantation of regulatory strategies for medicinal products, with a particular focus on rare diseases including oncology, and advanced therapies (cell and gene therapy products). Her experience spans from early development through commercialization including lead roles on the registration of several orphan drugs and regulatory expertise on both sides of the Atlantic. She holds a Master of Science in Environmental Health Sciences from the UCLA School of Public Health, as well as a BS in Chemical Engineering from the California Institute of Technology.

**Sheila Hanley, MPH**
Senior Advisor, Innovation Center
Centers for Medicare & Medicaid Services

Sheila Hanley, MPH is currently Senior Advisor in the Centers for Medicare & Medicaid Services (CMS) Innovation Center supporting the development and execution of the Center's strategic initiatives in priority areas including the alignment of private and public sectors in health transformation. She has contributed to the design and testing of multiple Innovation Center payment and delivery system models including initiatives in the areas of primary care, bundled payment, and value-based insurance design. As Director of the Policy and Programs Group she developed governance models for the oversight of the Center's portfolio of models and for the Health Care Innovation Awards (HCIA), a set of cooperative agreements originating in the private sector and testing promising care and reimbursement innovations. Prior to her work at the Innovation Center she led the design and implementation of new payment, care management, and data and reporting systems within Commercial, Medicare, and Medicaid managed care plans, and has held senior positions in acute care hospitals, responsible for clinical service development, strategic financial planning and payer contracts.

**Dan Ollendorf, PhD**
Chief Review Officer
Institute for Clinical and Economic Revier (ICER)

Dan Ollendorf has been the Chief Scientific Officer for the Institute of Clinical and Economic Review (ICER) since 2007. In this role, he is responsible for the conduct of systematic reviews of the comparative effectiveness of high impact health care technologies, integration of decision analysis and budgetary impact modeling into reviews of clinical evidence, engagement and collaboration with multiple stakeholders, and coordination as well as scientific oversight of the broader health technology assessment process. Dan manages a multidisciplinary team of scientists at ICER, and serves as primary liaison with academic clinical epidemiologists and health economists. His 30 years of health care experience include work in the hospital, informatics, insurance, managed care, and consulting sectors.

Prior to joining ICER, Dan was Executive Director, Health Economics and Outcomes Research, for IMS Health, where he was responsible for the operations of a $20 million franchise as well as the successful integration of a US consulting practice. He has also served as Vice President of Applied Research at PharMetrics (now a unit of IMS), where he managed the scientific team conducting a variety of research initiatives using integrated claims data; and as a senior consultant at Policy Analysis Inc. (PAI), where he designed and conducted health-economic, quality-of-life, and retrospective database analyses in a variety of therapeutic areas.

Dan holds a Ph.D. in clinical epidemiology from the University of Amsterdam, a Master's of Public Health from Boston University, and a Bachelor of Arts from the University of Rochester. He has authored over 50 peer-reviewed articles in major journals, and was on the Editorial Board of the Journal of Managed Care Pharmacy from 2009-2012. Dan currently serves on the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) HTA Council Working Group, and the Policy Forum of Health Technology Assessment International (HTAi).

**Krystyn J. Van Vliet, PhD**
Associate Provost
Professor of Materials Science and Engineering and Biological Engineering
Director of Manufacturing Innovation, MIT Innovation Initiative
Massachusetts Institute of Technology

Dr. Van Vliet earned her Sc.B. in Materials Science & Engineering from Brown University (1998) and her PhD in Materials Science & Engineering from MIT (2002). At MIT, Van Vliet was a National Defense Science & Engineering Graduate Fellow, was President of the Graduate Materials Council, and won the MRS Gold Medal for her thesis research. Her MIT thesis work with Prof. Subra Suresh established the experimental and computational basis for predicting homogeneous nucleation of dislocations (plasticity carrying defects) in crystalline metals. She then conducted postdoctoral research with Dr. Marsha Moses at Boston Children's Hospital, where she developed new experimental approaches to measure the effects of mechanical strain on cells that comprise blood vessels.