Advancing the Science of Patient Input in Medical Product R&D: Towards a Research Agenda - A Workshop

Committee

Cynthia Grossman

Co-Chair

Cynthia Grossman, Ph.D., is director, Science of Patient Input at FasterCures. Prior to joining FasterCures, Grossman was chief of the HIV Care Engagement and Secondary Prevention Program in the Division of AIDS Research at the National Institute of Mental Health. Her grant portfolio focused on research to improve the lives of people living with HIV/AIDS, including reducing the risk of onward transmission. She has spent her career encouraging research to address the unmet patient needs related to mental health, stigma, and other social determinants of health. She has also played a lead role in defining the social and behavioral scientific agenda for microbicides as HIV prevention as well as HIV cure related research. Grossman hold a bachelor’s degree in psychology and biology from Earlham College, a doctoral degree in clinical psychology from the University of Vermont and completed her postdoctoral work at Brown University. She works at the Institute's Washington, DC office.

Marilyn A. Metcalf

Co-Chair

Marilyn Metcalf, Ph.D. I am the U.S. spokesperson for GlaxoSmithKline's (GSK's) Patients in Partnership team. We leverage the company's experience collaborating with patients to grow consistent best practices throughout the organization and beyond, working with patients as expert stakeholders in creating medicines. As a family member and care partner of people who have lived with life-threatening illnesses, I am committed to partnering with patients to enable clear understanding of our medicines and how they can meet people's health goals. I am a member of GSK's Global Safety Board and participate in a number of alliances including Patient Focused Medicine Development; Patients as Partners; FasterCures; National Health Council; National Academies of Sciences, Engineering, and Medicine; TransCelerate; PhRMA; Drug Information Association; and Council for International Organizations of Medical SciencesWorking Group XI. Previously I was Family Health International's project director of an NIH master contract for HIV vaccine research, primarily in lower- and middle-income countries. At theformer GlaxoWellcome I studied the safety and efficacy, health economics, and quality of life effectsof HIV, oncology, and respiratory therapies. In 2001, I moved with my family to the U.K. to rebuildGSK's international Decision Sciences team. After returning to the U.S., I went to Centocor to lead their R&D Portfolio Management team. I came back to GSK and formed our Benefit Risk Evaluation team, then led GSK's Pharmacovigilance Centre of Innovation. I began my current role in June 2017.

Marc Boutin

Member

Marc M. Boutin, J.D., is the Chief Executive Officer of the National Health Council. He has been a leading voice for greater patient involvement at every stage of the health care continuum, starting with the development of new drugs, to regulatory oversight of health care delivery, to shared decision-making at the point of care. Under his leadership, the National Health Council has convened a broad range of stakeholders to create and effectively implement pragmatic strategies and public policy that address diverse issues, such as enhancing patient engagement, advancing the development of new treatments, and developing a betterhealth delivery system to meet the needs of people with chronic conditions. Boutin has a long history of board and committee service. Currently he serves as a member of the Patient Centered Outcomes Research Institute (PCORI) Patient Engagement Advisory Panel, FasterCures Benefit- Risk Advisory Council, and the Medical Device Innovation Consortium (MDIC) Patient-Centered Benefit-Risk Steering Committee. Boutin has been actively involved inpatient advocacy organization management, health advocacy, and both federal and state policy throughout his career. He is a founding member of the international Patient-Focused Medicine Development consortium and has served on the Governing Board of the International Alliance of Patients' Organizations as a member and treasurer. He is also a former member of the Partnership to Fight Chronic Disease Board of Directors, the Humana Cares Clinical Advisory Board, the eHealth Initiative Leadership Council, Community Health Charities Board of Directors, Healthcare Systems Research Collaboratory, and the North America Advisory Board to the Drug Information Association.

Kenneth Getz

Member

Kenneth A. Getz, M.B.A., is the Director of Sponsored Research Programs and an Associate Professor at the Tufts Center for the Study of Drug Development where he studies R&D management practices; pharmaceutical and biotechnology company operating models; and global investigative site, outsourcing, and study volunteer practices, trends and policies. Ken is also the chairman of CISCRP – a nonprofit organization that he founded to educate and raise public awareness of the clinical research enterprise — and the founder and owner of CenterWatch, a leading publisher in the clinical trials industry. A well-known speaker at conferences, symposia, universities and corporations, Ken has published extensively in peerreview journals, the trade press, and books. He holds a number of board appointments in the private and public sectors, is on the editorial boards of Contemporary Clinical Trials, Research Practitioner, the Drug Information Journal, Pharmaceutical Medicine and writes a column for Applied Clinical Trials that was a 2010 Neal Award finalist. Ken received an M.B.A. from the J.L. Kellogg Graduate School of Management at Northwestern University and a bachelor’s degree, Phi Beta Kappa, from Brandeis University. Prior to founding CenterWatch, Ken worked for over seven years in management consulting where he assisted biopharmaceutical companies develop and implement business strategies to improve clinical development performance.

Mats Hansson

Member

Mats Hansson, PH.D., is the director of the Centre for Research Ethics & Bioethics and has conducted extensive research in biomedical ethics as principal investigator in several multi-disciplinary research projects dealing with issues ranging from ethical, social and legal aspects of the implementation of genetic diagnosis in clinical practice and the use of human tissue materials in research, to clinical and medical ethics. Dr. Hansson is Professor of Biomedical Ethics, funded by Uppsala University and the Uppsala County Council together. He also works as a clinical consultant at Akademiska sjukhuset (Uppsala University Hospital). Dr. Hansson leads workpackages on ethical, legal and social issues in several EU projects on biobank and registry research. He is co-coordinator of the Innovative Medicines Initiative PREFER project, the principal investigator in Mind the Risk, and one of the co-ordinators of BBMRI-ERIC's ELSI common service. He holds an undergraduate degree in biology (1974) and a doctoral degree of theology (1991).

Lynn D. Hudson

Member

Lynn D. Hudson, Ph.D., serves as the Chief Science Officer for the Critical Path Institute (C-Path) and the Executive Director of the International Neonatal Consortium (INC) and the Multiple Sclerosis Outcome Assessments Consortium (MSOAC). She started at C-Path by overseeing the first regulatory qualification of an imaging biomarker for patient enrichment in clinical trials for Alzheimer's disease. Recent collaborative efforts include launching INC and co-chairing the Scientific Advisory Committee of CFAST, the partnership between C-Path and CDISC for creating and maintaining therapeutic area data standards. Lynn graduated with a B.S. in Biochemistry from the University of Wisconsin and a Ph.D. in Genetics and Cell Biology from the University of Minnesota, and trained at Harvard Medical School and Brown University. As Chief of the Developmental Genetics Section at the National Institute of Neurological Disorders and Stroke, she conducted research to define the network of genes involved in neural development. She served as an officer for the American Society for Neurochemistry and the PMD Foundation, and as an advisor for a number of granting agencies, including NIH, NSF, and the National MS Society. At the National Institutes of Health, Lynn directed the Office of Science Policy Analysis from 2006-2011. Presently Lynn represents C-Path on the board of BIOSA, the Bioindustry Organization of Southern Arizona. She has a Research Professor appointment in the College of Medicine at the University of Arizona, and was honored by AZBIO as the 2015 Arizona Bioscience Leader of the Year.

Theresa M. Mullin

Member

Theresa Mullin, Ph.D., serves as Associate Director for Strategic Initiatives in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). She oversees areas of strategic interest to external stakeholders. She leads the Patient-Focused Drug Development initiative, which includes work related to the FDA Reauthorization Act and implementation of the 21st Century Cures Act. She also leads CDER's International Program. Dr. Mullin previously served as director of CDER's Office of Strategic Program for almost a decade. Under her leadership, the office became a critical part of CDER's sustained effort to modernize drug regulatory operations. Before joining CDER in 2007, Dr. Mullin was Assistant Commissioner for Planning in FDA's Office of the Commissioner. Dr. Mullin received her bachelor's degree, magna cum laude, in economics from Boston College, and she has a Ph.D. in public policy analysis from Carnegie-Mellon University. Dr. Mullin received the Senior Executive Service Presidential Rank Award for Meritorious in 2006 and for Distinguished Service in 2011.

William Riley

Member

William T. Riley, Ph.D., was appointed Associate Director for Behavioral and Social Sciences Research, and Director of the Office of Behavioral and Social Sciences Research (OBSSR) at the National Institutes of Health (NIH) in August, 2015. Under his leadership, the OBSSR instituted its third and current strategic plan Download PDF (997 KB), which reflects key research challenges that the Office is uniquely positioned to address over the next five years, along with four foundational processes to enhance and support these scientific priorities as well as the OBSSR's broader mission. Since joining the NIH in 2005, he has served in extramural leadership positions at the National Institute of Mental Health (NIMH), the National Heart, Lung, and Blood Institute (NHLBI), and the National Cancer Institute (NCI). He has contributed to several trans-NIH initiatives including serving as Chief Science Officer for the Patient-Reported Outcomes Measurement Information System (PROMIS) and as NIH Interim Deputy Director of the Precision Medicine Initiative (PMI, now called the All of Us Research Program). He has been the recipient of several NIH Director's Awards including recognition for his work on the PROMIS and PMI initiatives. Dr. Riley received his undergraduate degree in Psychology and Sociology from James Madison University, and his M.S. and Ph.D. in Clinical Psychology from Florida State University. He interned in Medical Psychology at Baylor College of Medicine. He has served on the faculty of the Medical College of Georgia and Virginia Commonwealth University. After 15 years in academic medical schools, he became Director of Research at PICS, Inc., a health behavior research and development firm. Dr. Riley holds an appointment as Professorial Lecturer in the School of Public Health at The George Washington University. Dr. Riley's research has contributed significantly to the behavioral and social sciences, particularly in the application of digital technologies to behavioral assessment and intervention. Among his over 130 publications, he published the first application of text messaging for smoking cessation, and a highly cited article on the limitations of current health behavior theories to mobile health (mHealth) interventions.

Roslyn F. Schneider

Member

Roslyn Schneider,M.D., joined Pfizer in 2006 and is the Global Patient Affairs Lead on Pfizer’s Medical Leadership Team of the Chief Medical Office (CMO). In this newly created role, Dr. Schneider drives patient centricity and integration of the voice of the patient throughout the lifecycle of medicines and their development. Just prior to this she worked with the CMO on Medical Strategy and has held other leadership roles in Medical Affairs and Medicine Development at Pfizer. Dr. Schneider received her Bachelor of Science from the Sophie Davis School of Biomedical Education of the City College of New York, M.D. from Mount Sinai School of Medicine, and later her M.Sc. in Pharmaceutical Medicine from Hibernia College. Dr. Schneider is a retired Clinical Professor of Medicine of Albert Einstein College of Medicine, an Internist, Pulmonologist, Intensivist, and cared for patients at Beth Israel Medical Center, NY, for twenty years. She presented and published primarily in the areas of pulmonary complications of HIV infection, venous thromboembolic disease, medical ethics and medical education. Dr. Schneider was a Program Director for the Fellowship in Pulmonary and Critical Care, the Residency in Internal Medicine, and Assistant Chair of the Department of Medicine. She is a fellow of both the American College of Physicians and the American College of Chest Physicians where she chairs the Clinical Research Network. She also serves as Secretary on the Board of Trustees of the Physician Assistant Foundation, and is on the Advisory Council of the Keck Graduate Institute.

Suzanne Schrandt

Member

Suzanne Schrandt, J.D., is Patient Engagement Director at the Arthritis Foundation. She was previously Deputy Director, Patient Engagement for the Patient-Centered Outcomes Research Institute, where she helped to launch key efforts including the Engagement Rubric. Ms. Schrandt's patient engagement focus stems from her own rheumatological diagnosis at age 14. Prior posts include roles in health and disability law and policy, genetics, and public health. Schrandt is chair of the International Society for Pharmacoeconomics and Outcomes Research Patient Roundtable and a member of the FDA’s Patient Engagement Advisory Committee.

Lana Skirboll

Member

Lana Skirboll, Ph.D., M.S., is Vice President of Academic and Scientific Affairs at Sanofi, where she works on policy issues of importance to innovation. She formerly served as Director of Science Policy at the National Institutes of Health (NIH), where she was responsible for identifying policy issues relevant to the support and conduct of research, analyzing and recommending and creating new policies that advance the interest of the Agency. These included human subject protections, the privacy and confidentiality of research records, conflicts of interest, human embryo research, cloning and fetal tissue research, genetics, health, and society, dual use research, gene therapy and nanotechnology, comparative effectiveness research, personalized medicine, among others.Dr. Skirboll played a leadership role in NIH's organizational strategic planning and evaluation, where, for example, she developed NIH's efforts to measure and report on Agency performance. She also worked with the NIH Director, Elias Zerhouni, to design and implement the "Roadmap for Medical Research." She initiated the development of a new program on Return on Investment to explore NIH's impact on local economies and national competitiveness. She was responsible for developing and coordinating the NIH Public-Private partnership program, which leveraged NIH investments by working with industry. In addition, her team ran a small, but highly creative, science education program that worked nation-wide to develop materials for students and teachers on behalf of national science literacy and the pipeline of new young scientists, as well as creating opportunities with local students to learn about careers in science. As Acting Director of the NIH Division of Program Coordination, Planning, and Strategic Initiatives, she led national efforts to identify and address emerging scientific opportunities and rising public health challenges that cut across institutes, including the management of nearly 0.75 billion dollars in research funds. In addition, Dr. Skirboll was also responsible for NIH offices that coordinate research and activities related to research on AIDS, behavioral and social sciences, women's health, disease prevention, rare diseases, and dietary supplements. She also led NIH's burgeoning efforts to design and implement a program in Portfolio Analysis to inform Agency investments. Dr. Skirboll was trained in Pharmacology and Neuroscience. She completed her Ph.D. at Georgetown University Medical School, followed by post-doctoral work and research positions at Yale University, the Karolinska Institute (Sweden), and the National Institute of Mental Health. She is the author of more than 70 peer reviewed scientific publications.

Pamela Tenaerts

Member

Pamela Tenaerts, M.D., M.B.A., is Executive Director of the Clinical Trials Transformation Initiative (CTTI). Dr. Tenaerts works closely with the CTTI Executive Committee to develop and implement strategies to accomplish CTTI's mission. She provides senior level oversight of the day-to- day operations of CTTI and orchestrates efforts to effectively engage all interested stakeholders to improve the conduct of clinical trials. She is a member of PCORI's CTAP expert post-award subcommittee and MIT's Collaborative Initiatives Clinical Trials Process Expert Advisory Board, a Member of the Advisory Council North America, DIA. With more than 20 years' experience in the conduct of clinical trials across a number of sectors, she practiced medicine in both the emergency department and private practice setting for several years before embarking on a career in research. Most recently Dr. Tenaerts oversaw European operations for CoAxia, a medical device company focused on cerebral ischemia. She received her MD from Catholic University of Leuven, Belgium, and a M.B.A. from the University of South Florida. She speaks five languages and has obtained Six Sigma Green Belt certification.

John Wagner

Member

John Wagner, M.D., PH.D., received his M.D. from Stanford University School of Medicine and Ph.D. from the Johns Hopkins University School of Medicine. Postgraduate training included Internal Medicine Internship and Residency, as well as Molecular and Clinical Pharmacology Postdoctoral Fellowships at Stanford. He began his professional career in academic research on Cystic Fibrosis and has continued in the pharmaceutical industry, largely in the context of drug development as well as biomarkers. Currently, Dr. Wagner is Senior Vice President and Head, Clinical and Translational Sciences, Takeda Pharmaceutical International. He is also President, the American Society for Clinical Pharmacology and Therapeutics (ASCPT), a premier translational medicine and clinical pharmacology scientific association in the US. Dr. Wagner is also on the adjunct faculty at Harvard - Massachusetts Institute of Technology. Previously, he was Senior Consultant to the Institute of Medicine, Vice President and Head, Early Development Pipeline and Projects and Head, Global Project Management at Merck & Co., Inc., co-chair of Merck's early development governance committee, Vice President and Head, Clinical Pharmacology, at Merck & Co., Inc and Acting Modeling and Simulation Integrator, Strategically Integrated Modeling and Simulation. He is the past chair of the PhRMA Clinical Pharmacology Technical Group, past chair of the adiponectin work group for the Biomarkers Consortium, past committee member of the National Academies Institute of Medicine Committee on Qualification of Biomarkers and Surrogate Endpoints in Chronic Disease, and current full member of the National Academies Institute of Medicine National Cancer Policy Forum. Over 200 peer-reviewed publications detail work across a variety of therapeutic areas and disciplines.

Richard J. Willke

Member

Richard J. Willke, Ph.D., M.A., is Chief Science Officer of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Dr. Willke has more than 25 years of experience in the life sciences arena and has specialized in outcomes research in a succession of group leadership roles with Pfizer and its legacy companies. At ISPOR, Dr. Willke is responsible for designing and implementing strategic initiatives related to scientific research and content priorities that will advance the Society’s mission of promoting health economics and outcomes research excellence to improve decision making for health globally. Previously, Dr. Willke was Vice President, Outcomes & Evidence Cluster Lead at Pfizer for its Global Health & Value division. He has also served in a number of leadership roles with affiliated organizations, includin

the Chair of ISPOR Institutional Council (2010), ISPOR Board of Directors (2007-2009), and Chair of the PhRMA Health Outcomes Committee (2002-2004).Prior to joining industry, Dr. Willke served as Department Director in the Center of Health Policy Research at the American Medical Association and held research and teaching positions at The Ohio State University. Dr. Willke earned a Ph.D. and M.A. in economics from Johns Hopkins University. He has authored more than 80 scholarly publications that examine the science and methodologies of health

economics and outcomes research.