Sharing Clinical Research Data - A Workshop

Committee

Jeffrey S. Nye

Co-Chair

Jeffrey S. Nye, M.D., Ph.D., is vice president, neuroscience innovation and partnership strategy, at Janssen Research & Development LLC, a Johnson & Johnson (J&J) pharmaceutical company. He is responsible for the strategy and implementation of external R&D in the neurosciences, aiming to expand the pipeline with novel business relationships, venture, academic and public-private partnerships, and risk-shared outsourcing. Previously, Dr. Nye was chief medical officer and co-head of the East Coast Research and Early Development unit at J&J pharma. Prior roles include vice president of experimental medicine, vice president of compound development for Galantamine (Razadyne/Reminyl), a therapy for Alzheimer's disease, and for Topamax, an epilepsy and migrainemedicine. He previously served as a director of CNS Discovery Genomics and Biotechnology at Pharmacia. Prior to joining the pharmaceutical industry, Dr. Nye was a tenured associate professor of molecular pharmacology, biological chemistry, and pediatrics (neurology) at Northwestern University and Children's Memorial Hospital. He received his bachelor's degree in biochemistry and master's degree in pharmacology from Harvard, and his M.D. and Ph.D. (with Solomon Snyder) from the Johns Hopkins University School of Medicine. He served as a pediatrics resident, postdoctoral fellow (with Richard Axel), and assistant professor of pediatrics in neurology at the College of Physicians and Surgeons of Columbia University. Dr. Nye has published more than 60 peer-reviewed papers on topics spanning basic and clinical research, and has led pharma programs in discovery through clinical development. He has served on numerous study sections and advisory panels, and currently serves as a councilor of the British Association of Psychopharmacology. He is the co-chair of the New York Academy Alzheimer's Leadership council.

Sharon Terry

Co-Chair

Sharon F. Terry, M.A., is president and CEO of the Genetic Alliance, a network of more than 10,000 organizations, 1,200 of which are disease advocacy organizations. Genetic Alliance improves health through the authentic engagement of communities and individuals. It develops innovative solutions through novel partnerships, connecting consumers to smart services. She is the founding CEO of PXE International, a research advocacy organization for the genetic condition pseudoxanthoma elasticum (PXE). As codiscoverer of the gene associated with PXE, she holds the patent for ABCC6 and has assigned her rights to the foundation. She developed a diagnostic test and is conducting clinical trials. Ms. Terry is also a cofounder of the Genetic Alliance Registry and Biobank. She is the author of more than 90 peer-reviewed articles. In her focus at the forefront of consumer participation in genetics research, services, and policy, she serves in a leadership role on many of the major international and national organizations, including the Institute of Medicine (IOM) Health Sciences Policy Board, the National Coalition for Health Professional Education in Genetics board, and the International Rare Disease Research Consortium Interim Executive Committee. She is a member of the IOM Roundtable on Translating Genomic-Based Research for Health. She is on the editorial boards of several journals. She was instrumental in the passage of the Genetic Information Nondiscrimination Act. In 2005, she received an honorary doctorate from Iona College for her work in community engagement; the first Patient Service Award from the University of North Carolina Institute for Pharmacogenomics and Individualized Therapy in 2007; the Research!America Distinguished Organization Advocacy Award in

Josephine P. Briggs

Member

Josephine P. Briggs, M.D., is director of the National Center for Complementary and Alternative Medicine (NCCAM), and acting director,
Division of Clinical Innovation, National Center for Advancing Translational Sciences, National Institutes of Health (NIH). An accomplished researcher and physician, Dr. Briggs received her A.B. in biology from Harvard–Radcliffe College and her M.D. from Harvard Medical School. She completed her residency training in internal medicine and nephrology at the Mount Sinai School of Medicine, followed by a fellowship at Yale University. She then worked as a research scientist at the Physiology Institute at the University of Munich. In 1985, Dr. Briggs moved to the University of Michigan, where she held several academic positions, including associate chair for research in the Department of Internal Medicine and professorships in the Division of Nephrology, Department of Internal Medicine, and the Department of Physiology. She joined the NIH in 1997 as director of the Division of Kidney, Urologic, and Hematologic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases. In 2006, Dr. Briggs accepted a position as senior scientific officer at the Howard Hughes Medical Institute. In 2008, she returned to the NIH as director of the NCCAM. Dr. Briggs has published more than 175 research articles, book chapters, and scholarly publications. She has served on the editorial boards of several journals, and wasdeputy editor for the Journal of Clinical Investigation. Dr. Briggs is an elected member of the American Association of Physicians and the American Society of Clinical Investigation and a fellow of the American Association for the Advancement of Science. She is a recipient of many awards and prizes, including the Volhard Prize of the German Nephrological Society, the Alexander von Humboldt Scientific Exchange Award, and NIH Director’s Awards for her role in the development of the Trans-NIH Type I Diabetes Strategic Plan and her leadership of the Trans-NIH Zebrafish committee. Dr. Briggs is also a member of the NIH Steering Committee, the highest governing board at the NIH.

Timothy Coetzee

Member

Steven N. Goodman

Member

Steven N. Goodman, M.D., M.H.S., Ph.D., is professor of medicine and health policy, and research and associate dean for clinical and translational research at Stanford University. Before joining Stanford in 2011, Dr. Goodman spent two decades on the Johns Hopkins medical faculty as professor of oncology in the division of biostatistics, with appointments in the departments of Pediatrics, Biostatistics, and Epidemiology in the Johns Hopkins Schools of Medicine and Public Health. He has been editor of Clinical Trials: Journal of the Society for Clinical Trials since 2004 and senior statistical editor for the Annals of Internal Medicine since 1987. He has served on a wide range of Institute of Medicine committees, including Agent Orange and Veterans, Immunization Safety, the Committee on Alternatives to the Daubert Standards, Treatment of PTSD (Posttraumatic Stress Disorder) in Veterans, and most recently cochaired the Committee on Ethical and Scientific Issues in Studying the Safety of Approved Drugs, whose report was released in 2012. Dr. Goodman was appointed by the Government Accountability Office to serve on the Methodology Committee of the Patient Centered Outcomes Research Institute and is a scientific advisor to the Medical Advisory Panel of the National Blue Cross/Blue Shield Technology Evaluation Center. He served on the Surgeon General’s committee to write the 2004 report on the health consequences of smoking. Dr. Goodman received a B.A. from Harvard; an M.D. from New York University; trained at Washington University in pediatrics, in which he was board certified; and received an M.H.S. in biostatistics and a Ph.D. in epidemiology from Johns Hopkins University. He writes and teaches on evidence evaluation
and inferential, methodologic, and ethical issues in epidemiology and clinical research.

Robert A. Harrington

Member

Robert A. Harrington, M.D., is the Arthur L. Bloomfield Professor of Medicine and chair of the Department of Medicine at Stanford University. He received his undergraduate degree in English from the College of the Holy Cross in Worcester, MA. He attended Dartmouth Medical School and received his M.D. from Tufts University School of Medicine in 1986. He was an intern, resident, and the chief medical resident in internal medicine at the University of Massachusetts Medical Center. He was a fellow in cardiology at Duke University Medical Center, where he received training in interventional cardiology and research training in the Duke Databank for Cardiovascular Diseases. Dr. Harrington was previously the director of the Duke Clinical Research Institute. His research interests include evaluating antithrombotic therapies to treat acute ischemic heart disease and to minimize the acute complications of percutaneous coronary procedures; studying the mechanism of disease of the acute coronary syndromes; understanding the issue of risk stratification in the care of patients with acute ischemic coronary syndromes; and trying to better understand and improve on the methodology of clinical trials. He is the recipient of a National Institutes of Health Roadmap contract to investigate “best practices” among clinical trial networks. He has authored more than 400 peer-reviewed manuscripts, reviews, book chapters, and editorials. He is an associate editor of the American Heart Journal and an editorial board member for the Journal of the American College of Cardiology. He is a senior editor of the 13th edition of Hurst’s The Heart. He is a fellow of the American College of Cardiology, the American Heart Association, the European Society of Cardiology, the Society of Cardiovascular Angiography and Intervention, and the American College of Chest Physicians. He recently served as a member and the chair of the Food and Drug Administration Cardiovascular and Renal Drugs Advisory Committee.

Lynn D. Hudson

Member

Lynn D. Hudson, Ph.D., serves as the chief science officer for the Critical Path Institute and executive director of the Multiple Sclerosis Consortium. She received a B.S. in biochemistry at the University of Wisconsin, a Ph.D. in genetics and cell biology at the University of Minnesota, and postdoctoral training at Harvard Medical School and Brown University. For most of her career, Dr. Hudson has been a bench neuroscientist at the National Institutes of Health (NIH), where she directed the Office of Science Policy Analysis from 2006 to 2011. As a major source for policy analysis within the NIH Office of the Director, her office covered a wide spectrum of sensitive and emerging issues and oversaw a number of programs, including the American Association for the Advancement of Science/NIH Science Policy Fellowship program, the NIH's contract with the National Academy of Sciences, and the Public–Private PartnershipProgram. Her policy team's awards cite contributions to the NIH's congressional justification, biennial report, implementation of the NIH Reform Act, stem cell guidelines, and comparative effectiveness research. Dr. Hudson has conducted research in the National Institute of Neurological Disorders and Stroke (NINDS) intramural program, where she was chief of the Section of Developmental Genetics for 16 years. She received the NIH Merit Award for her discovery of the causative mutations in the neurologic disorder Pelizaeus-Merzbacher Disease (PMD), and an NINDS Award for educational outreach efforts. Her research focused on defining the network of genes involved in the development of glial cells, with the goal of designing strategies to overcome glial dysfunction in inherited or acquired neurological diseases. She served as an officer for the American Society for Neurochemistry, as an officer on the scientific advisory board of the PMD Foundation, and as an advisor for a number of granting agencies and disease foundations, including the National Multiple Sclerosis Society.

Charles Hugh-Jones

Member

Charles Hugh-Jones, M.D., is vice president and head, Medical Affairs North America, Oncology, Hematology, and Solid Organ Transplant at Sanofi. He has previously served as vice president and head, Oncology Medical Affairs, North America, for Sanofi-Aventis; vice president of brand management and vice president of medical affairs at Enzon Pharmaceuticals; executive director, Medical Affairs, at Schering AG/ Berlex/Bayer-Schering; director of medical affairs for Schering AG, Global Business Unit; senior medical advisor for Schering AG, United Kingdom; and specialist registrar at Hammersmith Hospital, United Kingdom. Dr. Hugh-Jones received his M.D. from the University of London. He is board certified in internal medicine and has additional Higher Specialist Training (United Kingdom) in diagnostic and interventional radiology.

Jan Johannessen

Member

Harlan M. Krumholz

Member

Harlan Krumholz, M.D., is the Harold H. Hines, Jr., Professor of Medicine and director of the Robert Wood Johnson Clinical Scholars Program at Yale University School of Medicine, and director of the YaleNew Haven Hospital Center for Outcomes Research and Evaluation. His research focuses on determining optimal clinical strategies and identifying opportunities for improving the prevention, treatment, and outcome of cardiovascular disease. Using applied clinical research methods, his work seeks to provide critical information to improve the quality of health care, monitor changes over time, guide decisions about the allocation of scarce resources, and inform decisions made by patients and their clinicians. Studies from his research group have directly led to improvements in the use of guideline-based medications, the timeliness of care for acute myocardial infarction, the information available to patients who are making decisions about clinical options, the public reporting of outcomes measures, and the current national focus on reducing the risk of readmission. He has also advanced the application of quality improvement to the elimination of disparities. His work influenced several provisions in the health reform bill. Dr. Krumholz serves on the board of trustees of the American College of Cardiology, the board of directors of the American Board of Internal Medicine, and the board of governors of the Patient-Centered Outcomes Research Institute. He is an elected member of the Association of American Physicians, the American Society for Clinical Investigation, and the Institute of Medicine. He is a Distinguished Scientist of the American Heart Association and received its Distinguished Service Award. He received a B.S. from Yale, an M.D. from Harvard Medical School, and a master’s in health policy and management from the Harvard University School of Public Health.

Shawnmarie Mayrand-Chung

Member

James D. Neaton

Member

Richard Platt

Member

Richard Platt, M.D., M.Sc., is a professor and chair of the Department of Population Medicine, and executive director of the Harvard Pilgrim Health Care Institute. He is an internist trained in infectious diseases and epidemiology. His research focuses on developing multi-institution automated record linkage systems for use in pharmacoepidemiology, and for population-based surveillance, reporting, and control of both hospital and community-acquired infections. He is principal investigator of the Food and Drug Administration's (FDA's) Mini-Sentinel program, of a Centers for Disease Control and Prevention (CDC) Center of Excellence in Public Health Informatics, of the Agency for Healthcare Research and Quality HMO Research Network DEcIDE center, and of a CDC Prevention Epicenter. He is a member of the Institute of Medicine Roundtable on Value & Science-Driven Health Care, and of the Association of American Medical Colleges' Advisory Panel on Research. Dr. Platt formerly chaired the FDA Drug Safety and Risk Management Advisory Committee, a National Institutes of Health study section (Epidemiology and Disease Control 2), and the CDC Office of Health Care Partnerships steering committee, and co-chaired the Board of Scientific Counselors of the CDC National Center for Infectious Diseases.

William Z. Potter

Member

William Z. Potter, M.D., Ph.D., earned his B.A., M.S., M.D., and Ph.D. at Indiana University, after which he held positions of increasing responsibility and seniority in translational neuroscience over the next 25 years at the National Institutes of Health (NIH). While there, Dr. Potter was widely published and appointed to many societies, committees, and boards, which enabled him to develop a wide reputation as an expert in psychopharmacological sciences and champion the development of novel treatments for central nervous system (CNS) disorders. Dr. Potter left the NIH in 1996 to accept a position as executive director and Research Fellow at Lilly Research Labs, specializing in the Neuroscience Therapeutic Area. In 2004 he joined Merck Research Labs (MRL) as vice president of clinical neuroscience, and in 2006, he took on the newly created position of vice president of Translational Neuroscience, from which he retired in 2012. His experience at Lilly and MRL in identifying, expanding, and developing methods of evaluating CNS effects of compounds in human brains cover state-of-the-art approaches across multiple modalities. These include brain imaging and cerebrospinal fluid proteomics (plus metabolomics) as well as development of more sensitive clinical, psychophysiological, and performance measures allowing a range of novel targets to be tested in a manner that actually addresses the underlying hypotheses. He has become a widely recognized champion for the position that more disciplined hypothesis testing of targets in humans is the best near-term approach to moving CNS drug development forward for important neurologic and psychiatric illnesses.

Frank W. Rockhold

Member

Frank W. Rockhold, Ph.D., is senior vice president, global clinical safety and pharmacovigilance at GlaxoSmithKline (GSK) Pharmaceuticals Research and Development. This includes case management, signal detection, safety evaluation, and risk management for all development and marketed products. He is also co-chair of the GSK Global Safety Board. In his 20 years at GSK, he has also held management positions within the Statistics & Epidemiology Department and Clinical Operations, both in R&D and in the U.S. pharmaceutical business, and most recently as interim head of the Cardiovascular and Metabolic Medicines Development Center. Dr. Rockhold previously held positions of research statistician, Lilly Research Laboratories, and executive director of biostatistics, data management, and health economics, Merck Research Laboratories. He has a B.A. in statistics from the University of Connecticut, an Sc.M. in biostatistics from Johns Hopkins University, and a Ph.D. in biostatistics from the Medical College of Virginia. He has held academic appointments at Butler University; Indiana University; adjunct professor of health evaluation sciences, Penn State University; and adjunct scholar in the Department of Epidemiology and Biostatistics at the University of Pennsylvania. Dr. Rockhold is currently affiliate professor of biostatistics at the Virginia Commonwealth University Medical Center. He is a past chair of the board of directors of the Clinical Data Interchange Standards Consortium and a member of the National Library of Medicine Advisory Group for ClinicalTrials.Gov. He is past president, Society for Clinical Trials; past chair, Pharmaceutical Research and Manufacturers Association (PhRMA) Biostatistics Steering Committee, and a member of the ICH E-9 and E-10 Expert Working Groups. He also served as associate editor for Controlled Clinical Trials. He is a fellow of the American Statistical Association and a fellow of the Society for Clinical Trials. He is also a recipient of the PhRMA Career Achievement award. He has more than 150 publications and abstracts.

Michael Rosenblatt

Member

Michael Rosenblatt, M.D., is executive vice president and chief medical officer of Merck & Co., Inc. He is the first person to serve in this role for Merck. Previously he served as dean of Tufts University School of Medicine. Prior to that, he held the appointment of George R. Minot Professor of Medicine at Harvard Medical School and chief of the Division of Bone and Mineral Metabolism Research at Beth Israel Deaconess Medical Center (BIDMC). He served as the president of BIDMC from 1999 to 2001. Previously, he was the Harvard faculty dean and senior vice president for academic programs at CareGroup and BIDMC, and a founder of the Carl J. Shapiro Institute for Education and Research at Harvard Medical School and BIDMC, a joint venture whose mission is to manage the academic enterprise and promote academic innovation. Earlier, he served as director of the Harvard–Massachusetts Institute of Technology (MIT) Division of Health Sciences and Technology, during which time he led a medical education organization for M.D., Ph.D., and M.D.–Ph.D. training jointly sponsored by Harvard and MIT. Previously, he was senior vice president for research at Merck Sharp & Dohme Research Laboratories, where he co-led the worldwide development team for alendronate (FOSAMAX), Merck's bisphosphonate for osteoporosis and bone disorders. In addition, he directed drug discovery efforts in molecular biology, bone biology and calcium metabolism, virology, cancer research, lipid metabolism, and cardiovascular research in the United States, Japan, and Italy. In leading most of Merck's international research efforts, he established two major basic research institutes, one in Tsukuba, Japan, and one near Rome, Italy. He also headed Merck Research's worldwide University and Industry Relations Department. He is the recipient of the Fuller Albright Award for his work on parathyroid hormone and the Vincent du Vigneaud Award in peptide chemistry and biology, and the Chairman's Award from Merck. His research is in the field of hormonal regulation of calcium metabolism, osteoporosis, and cancer metastasis to bone. His major research projects are in the design of peptide hormone antagonists for parathyroid hormone and the tumor-secreted parathyroid hormone-like protein; isolation/characterization of receptors and mapping hormone–receptor interactions; elucidation of the mechanisms by which breast cancer "homes" to bone; and osteoporosis and bone biology. He has been an active participant in the biotechnology industry, serving on the board of directors and scientific advisory boards of several biotech companies. He was a scientific founder of ProScript, the company that discovered bortezomib (Velcade), now Millennium Pharmaceutical's drug for multiple myeloma and other cancers. He was a member of the Board of Scientific Counselors of the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health. He has been elected to the American Society of Clinical Investigation and the Association of American Physicians; to fellowship in the American Association for the Advancement of Science and the American College of Physicians; and as president of the American Society of Bone and Mineral Research. He has testified before the U.S. Senate on U.S. biomedical research priorities, and served as a consultant to the U.S. President's Council of Advisors on Science and Technology. He previously served as Chief of the Endocrine Unit, Massachusetts General Hospital. He received his undergraduate degree summa cum laude from Columbia University and his M.D. magna cum laude from Harvard. His internship, residency, and endocrinology training were all at Massachusetts General Hospital.

Vicki Seyfert-Margolis

Member

Vicki L. Seyfert-Margolis, Ph.D., is senior advisor for science innovation and policy in the Food and Drug Administration Commissioner's Office. She focuses on initiatives in innovation, regulatory science, personalized medicine, scientific computing, and health informatics. Previously, she served as chief scientific officer at Immune Tolerance Network (ITN), a nonprofit consortium of researchers seeking new treatments for diseases of the immune system. At ITN, she oversaw the development of more than 20 centralized laboratory facilities, and the design and execution of biomarker discovery studies for more than 25 Phase II clinical trials. As part of the biomarker efforts, she established construction of a primer library of 1,000 genes that may be involved in establishing and maintaining immunologic tolerance and codiscoveredgenes thatmay mark kidney transplant tolerance. Dr. Seyfert-Margoliswas also an adjunct associate professor with the Department of Medicineat the University of California, San Francisco. She also served as director of the Office of Innovative Scientific Research Technologies at the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, where she worked to integrate emerging technologies into existing immunology and infectious disease programs. Dr. SeyfertMargolis completed her Ph.D. in immunology at the University of Pennsylvania's School of Medicine.

Deborah A. Zarin

Member

Deborah A. Zarin, M.D., is director of ClinicalTrials.gov and assistant director of clinical research projects at the Lister Hill National Center for Biomedical Communications in the National Library of Medicine. In this capacity, Dr. Zarin oversees the development and operation of an international registry of clinical trials. Previous positions include director of the Agency for Healthcare Research and Quality Technology Assessment Program and director of the American Psychiatric Association Practice Guidelines program. In these positions, Dr. Zarin conducted systematic reviews and related analyses in order to develop clinical and policy recommendations. Her academic interests are in the area of evidence-based clinical and policy decision making, and she is the author of more than 70 peer-reviewed articles. Dr. Zarin graduated from Stanford University and received her M.D. from Harvard Medical School. She completed a clinical decision-making fellowship, and is board certified in general psychiatry as well as in child and adolescent psychiatry