Jon D. Duke, MD, MS, Director, Drug Safety Informatics Lab, Regenstrief Institute; Assistant Professor of Medicine, Indiana University School of Medicine
Dr. Duke is an assistant professor at the Indiana University School of Medicine and currently serves as director of Regenstrief Institute's Drug Safety Informatics Lab. He also serves as Regenstrief's Chief Innovation Officer and leads the Merck-Regenstrief Partnership for Healthcare Research and Innovation. Dr. Duke graduated from Harvard Medical School and completed his residency in internal medicine at Brigham and Women's Hospital in Boston. He completed a National Library of Medicine Fellowship in Medical Informatics and a Masters in Human-Computer Interaction from Indiana University.

Dr. Duke's primary research focus is on the communication and personalization of drug safety information, particularly through clinical decision support and product labeling. His other area of research is EMR usability, and he oversaw the development of a next-generation order entry system incorporating novel features such as natural language processing, contextual alerting, and adaptive behaviors to improve patient safety and quality of care. In addition to academic journals, his work has been featured in popular media including the New York Times, National Public Radio, and Consumer Reports. Dr. Duke is fluent in Japanese and has done work with the medical informatics community in Japan. He continues to see patients as a practicing internist.

William DuMouchel, PhD, Chief Statistical Scientist, Oracle Health Sciences
Dr. DuMouchel's research focuses on statistical computing and Bayesian hierarchical models, including applications to meta-analysis and data mining. He is the inventor of the empirical Bayesian data mining algorithm known as GPS and its successor MGPS, which have been applied to the detection of safety signals in databases of spontaneous adverse drug event reports. These methods are now used within the FDA and industry. From 1996 through 2004 he was a senior member of the data mining research group at AT&T Labs. Before that, he was Chief Statistical Scientist at BBN Software Products, where he was lead statistical designer of software advisory systems for experimental design and data analysis called RS/Discover and RS/Explore. Dr. DuMouchel has been on the faculties of the University of California at Berkeley, the University of Michigan, MIT, and most recently was Professor of Biostatistics and Medical Informatics at Columbia University from 1994-1996.

He has authored approximately fifty papers in peer-reviewed journals and has also been an associate editor of the Journal of the American Statistical Association, Statistics in Medicine, Statistics and Computing, and the Journal of Computational and Graphical Statistics. Dr. DuMouchel is a member of the International Statistical Institute and is an elected fellow of the American Statistical Association and of the Institute of Mathematical Statistics. He has served on the National Research Council (NRC) Committee on Applied and Theoretical Statistics and on the Institute of Medicine Committee on Postmarket Surveillance of Pediatric Medical Devices and the NRC Committee on National Statistics. He received the Ph.D. in Statistics from Yale University.

Abraham Hartzema, PharmD, MSPH, PhD, FISPE, Professor and Eminent Scholar, Perry A. Foote Chair in Health Outcomes and Pharmacoeconomics, Department of Pharmaceutical Outcomes & Policy, College of Pharmacy, and the Department of Epidemiology and Biostatistics, College of Public Health and Health Professions, University of Florida

Dr. Hartzema investigates health outcomes with an emphasis on pharmacoepidemiology, passive and active drug safety surveillance systems, therapeutic risk management, and program evaluation. He has served as principal and co-investigator on major grants from the National Institutes of Health, AHRQ, foundations and the pharmaceutical industry. He has co-authored and edited three books, two of which are in multiple editions, two monographs, one of which is translated in several languages, and has published and presented over 100 chapters, journal articles, abstracts and presentations. He has served on the Scientific Board of the International Pharmaceutical Federation, and serves or served on eight editorial boards. He is the recipient of the 2007 UF Foundation Research Award. He is an elected Fellow of the International Society for Pharmacoepidemiology. In 2008-2009, he spent his sabbatical in the Immediate Office of the Food and Drug Administration's Commissioner working on the Sentinel system. Currently, Dr. Hartzema serves on the Council of the United States Pharmacopeia, and as senior advisor to the FDA CDRH.

David Madigan, PhD, Executive Vice President for Arts and Sciences and Dean of the Faculty of Arts and Sciences, Columbia University

Dr. Madigan received a bachelor's degree in Mathematical Sciences and a Ph.D. in Statistics, both from Trinity College Dublin. He has previously worked for AT&T Inc., Soliloquy Inc., the University of Washington, Rutgers University, and SkillSoft, Inc. He has over 100 publications in such areas as Bayesian statistics, text mining, Monte Carlo methods, pharmacovigilance and probabilistic graphical models. He is an elected Fellow of the American Statistical Association and of the Institute of Mathematical Statistics. He recently completed a term as Editor-in-Chief of Statistical Science.

Mark McClellan, MD, PhD, Senior fellow and Director of the Initiative on Value and Innovation in Health Care, Brookings Institution

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

Richard Moscicki, MD, Deputy Center Director for Science Operations, Center for Drug Evaluation and Research, FDA

Richard (Rich) A. Moscicki, M.D., joined the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), as Deputy Center Director for Science Operations in April 2013. A nationally recognized expert in clinical research and development, Dr. Moscicki is bringing his extensive scientific expertise and executive leadership skills to Center operations and direction and to effective development and implementation of CDER programs. Before joining CDER, Dr. Moscicki served as senior vice president (SVP), Head of Clinical Development at Genzyme Corporation. He joined Genzyme in 1992 as Medical Director, becoming Chief Medical Officer and SVP of Biomedical and Regulatory Affairs in 1996 and holding that post until 2011. During that time, Dr. Moscicki was responsible for worldwide global regulatory and pharmacovigilance matters and oversaw all aspects of clinical research and medical affairs for the company.

Dr. Moscicki received his medical degree from Northwestern University Medical School. He is board certified in internal medicine, diagnostic and laboratory immunology, and allergy and immunology. He completed his residency in Internal Medicine, followed by a four-year fellowship at Massachusetts General Hospital (MGH) in Clinical immunology and immunopathology. He remained on staff at MGH in Clinical Immunology and on the faculty of Harvard Medical School from 1979 until 2013.

Niklas Norén, PhD, Chief Science Officer and Head of Research Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden

Dr Norén is the Chief Science Officer and Head of Research with overall responsibility for the scientific direction of the Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Sweden. He holds a PhD in Mathematical Statistics from Stockholm University in 2007 and a Master's degree in Engineering Physics from Chalmers University of Technology in 2002. Dr Norén has worked in various positions at the Uppsala Monitoring Centre and affiliated organizations since 2002. He has published more than 20 peer-reviewed papers on exploratory analysis of observational medical data, including internationally awarded research of methods for duplicate detection and subgroup discovery.

Dr Norén serves as co-leader of Work package 3: Methods for signal detection and on the Steering Committee, in the Pharmacoepidemiological Research on Outcomes of Therapeutics (PROTECT). He is a member of the Editorial Board of Drug Safety since 2009, and was appointed external peer reviewer for the Council for International Organizations of Medical Sciences (CIOMS) VIII Working Group report on Signal Detection and Signal Management in Pharmacovigilance in 2008. He leads the Uppsala Monitoring Centre's contributions to the Observational Medical Outcomes Partnership (OMOP), and led the work packages on detecting substandard medicines and drug dependence from spontaneous reports, in the Monitoring Medicines project (European Commission's Seventh Framework Programme).

Robert T. O'Neill, PhD, Senior Statistical Advisor, CDER, US Food and Drug Administration

Dr. Robert O'Neill is currently the Senior Statistical Advisor to CDER in the Office of Translational Sciences in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration. Until June 2011 , Dr. O'Neill was the Director of the Office of Biostatistics which provides biostatistical and scientific computational leadership and support to all programs of CDER. Prior to October 1998 he was Director of the Office of Epidemiology and Biostatistics, responsible also for the post-market safety surveillance of new drugs. In 1989-1990, Dr. O'Neill was a visiting professor at the Department of Research, University Medical School, Basel, Switzerland, where he developed and presented numerous lectures and created a course series Topics in Therapy Evaluation and Review (TITER) for European pharmaceutical scientists, which was the model for the European Course In Pharmaceutical Medicine (ECPM), a degree granting graduate program. Dr. O'Neill was the ICH FDA topics leader for two guidances, E9 and E5. He is a fellow of the American Statistical Association (1985) and the Society for Clinical Trials (2013), a member of several professional societies, a past Member of the Board of Directors of the Society for Clinical Trials, the 2002 recipient of the Marvin Zelen Leadership Award in Statistical Science, and the 2004 Lowell Reed Lecture Awardee from the American Public Health Association.

J. Marc Overhage, MD, PhD, Chief Medical Informatics Officer, Siemens Healthcare

Dr. Overhage is the Chief Medical Informatics Officer for Siemens Healthcare. Prior to joining Siemens he was the founding Chief Executive Officer of the Indiana Health Information Exchange and was Director of Medical Informatics at the Regenstrief Institute, Inc., and a Sam Regenstrief Professor of Medical Informatics at the Indiana University School of Medicine.

He has spent over 25 years developing and implementing scientific and clinical systems and evaluating their value. With his colleagues from the Regenstrief Institute, he created a community wide electronic medical record (called the Indiana Network for Patient Care) containing data from many sources including laboratories, pharmacies and hospitals in central Indiana. The system currently connects a majority of acute care hospitals in central Indiana and includes inpatient and outpatient encounter data, laboratory results, immunization data and other selected data. In order to create a sustainable financial model, he helped create the Indiana Health Information Exchange, a not-for-profit corporation. In addition Dr. Overhage has developed and evaluated clinical decision support including inpatient and outpatient computerized physician order entry and the underlying knowledge bases to support them. He practiced general internal medicine for over 20 years including the ambulatory, inpatient and emergency care settings.

Over the last decade, Dr Overhage has played a significant regional and national leadership role in advancing the policy, standards, financing and implementation of health information exchange. He served on the National Committee for Vital and Health Statistics and the Health Information Technology Standards Committee as well as serving on the Board of Directors of the National Quality Form and being engaged in a number of national healthcare initiatives.

Christian Reich, MD, PhD, Global Head of Bioinformatics, AstraZeneca PLC
Dr. Reich has more than 15 years of experience in life science research and medicine. He was a practicing physician in Berlin and Ulm, Germany before moving to the European Bioinformatics Institute to work on the Human Genome Project. He then joined the biotech industry in 1998, where he worked in various positions on typical challenges in drug research and development, such as gene sequence and expression analysis, clinical trial design and analysis, systems biology, and outcome research, applying computational methods to large scale biological data. Since the beginning of this year, he is Head of Discovery Informatics at AstraZeneca. Dr. Reich received his bachelor's degree in preclinical training from Humboldt University in Berlin and holds his M.D. and doctorate from the Medical University of Lübeck, Germany where he focused his research on T-cell activation and regulation.

Patrick Ryan, PhD, Director and Head, Epidemiology Analytics, Janssen Research and Development
Dr. Ryan is leading efforts at Janssen to develop and apply analysis methods to better understand the real-world effects of medical products. As a Primary Investigator of OMOP, he is conducting methodological research to assess the appropriate use of observational health care data to identify and evaluate drug safety issues. He leads a team of researchers to support the Epidemiology department, the Janssen Research and Development organization, and broader research community by generating knowledge and facilitating access to real-world evidence about disease, health service utilization, and the effects of medical products through the analysis of healthcare data

Patrick received his undergraduate degrees in Computer Science and Operations Research at Cornell University, his Master of Engineering in Operations Research and Industrial Engineering at Cornell, and his PhD in Pharmaceutical Outcomes and Policy from University of North Carolina at Chapel Hill. Patrick has worked in various positions within the pharmaceutical industry at Pfizer and GlaxoSmithKline, and also in academia at the University of Arizona Arthritis Center.

Martijn Schuemie PhD; Associate Director, Epidemiology, Janssen Research and Development
Dr. Schuemie received his Master's degree in Economics from the Erasmus University in Rotterdam, and his PhD in Informatics from the Delft University of Technology. His past research includes phobia treatment using virtual reality, and text-mining in scientific literature. More recently, his work at the Erasmus University Medical Center focused on the re-use of electronic healthcare records (EHRs) for research. He was one of the principal investigators of the EU-ADR project, heading the development and comparison of statistical methods for signal detection using EHRs, and developed techniques for text-mining patient records. In 2012 he received a one-year fellowship from the FDA, which he spent at OMOP, and since the start of 2013 Dr. Schuemie has moved to the Epidemiology Department of Janssen Research & Development, where he is continuing his research in methods for observational research. Dr. Schuemie is one of the OMOP principal investigators.

Paul Stang, PhD, Vice-President, Global Epidemiology, Janssen Research and Development

Paul Stang, PhD has held a number of positions over the past 25 years in epidemiology and pharmacoepidemiology including the past 6 years as Senior Director of Epidemiology at Janssen Research and Development. Previously, Dr. Stang was a Vice-President at Cerner Corporation, which he joined after co-founding and serving as the Chief Scientific Officer of Galt Associates, a health care consulting and informatics start-up that was acquired by Cerner. He previously served in positions at other health care companies and academic medical centers including SUNY-Stony Brook Department of Neurosurgery, and the UNC Department of Neurosurgery. He holds adjunct faculty appointments at a number of institutions and is an elected Fellow of the International Society for Pharmacoepidemiology. Dr. Stang has published widely in epidemiology, health outcomes, impact of health on productivity, and communications. He holds degrees from UNC-Chapel Hill, Bowman Gray, and SUNY-Stony Brook.

Marc A. Suchard, MD, PhD, Professor in the Departments of Biostatistics, of Biomathematics and of Human Genetics in the UCLA Fielding School of Public Health and David Geffen School of Medicine at UCLA

Dr. Suchard earned his Ph.D in biomathematics from UCLA in 2002 and continued for a MD degree which he received in 2004. Prof. Suchard is in the forefront of high-performance statistical computing. Dr. Suchard is a leading Bayesian statistician who focuses on inference of stochastic processes in biomedical research and in the clinical application of statistics, having published over 125 research articles. His training in both Medicine and Applied Probability help bridge the gap of understanding between statistical theory and clinical practicality. He has been awarded several prestigious statistical awards such as the 2003 Savage Award, the 2006 and 2011 Mitchell Prizes, as well as a 2007 Alfred P. Sloan Research Fellowship in computational and molecular evolutionary biology and a 2008 Guggenheim Fellowship to further computational statistics. He received the 2011 Raymond J. Carroll Young Investigator Award and, recently, the 2013 Committee of Presidents of Statistical Societies (COPSS) Presidents' Award for outstanding contributions to the statistics profession by a person aged 40 or under. He is an elected Fellow of the American Statistical Association.

Alexander M. Walker MD, DrPH, Principal of World Health Information Science Consultants (WHISCON); Adjunct Professor of Epidemiology at Harvard School of Public Health

Dr. Walker is a Principal of World Health Information Science Consultants (WHISCON) and Adjunct Professor of Epidemiology at Harvard School of Public Health, where he was formerly a professor and Chair of the Department. Through WHISCON, Dr. Walker is serving as the scientific staff advisor to IMEDS (Innovation in Medical Evidence Development and Surveillance). Dr. Walker's research encompasses the safety of drugs, devices, vaccines, and medical procedures. Current studies include post-marketing safety studies for recently approved drug. Additional areas of research and expertise include natural history of disease, the impact of drug labeling and warnings on prescribing behavior, determinants of drug uptake and discontinuation, health effects of chemicals used in the workplace and statistical methods in epidemiology.

Dr. Walker received an MD degree from Harvard Medical School in 1974, and a doctorate of Public Health in Epidemiology from the Harvard School of Public Health in 1981. He was a statistical consultant for the New England Journal of Medicine from 1992 through 1996 and a Contributing Editor of The Lancet from 1999 through 2001. From 2000 through 2007, he served as Senior Vice President for Epidemiology at Ingenix. Dr. Walker has written or contributed to over 250 peer-reviewed articles in drug safety, epidemiology and occupational health, and is the author of a book of essays, Observation and Inference: An Introduction to the Methods of Epidemiology.