Developing Personalized Clinical Outcome Assessments
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Biographies

Heather Adams is an Associate Professor in the Department of Neurology at the University of Rochester School of Medicine and Dentistry. She is a member of the University of Rochester Batten Center (URBC) and serves on the Medical Advisory Board to the Batten Disease Support & Research Association. In addition to ongoing consultation and support to other investigators who study cognition and behavior in childhood, her primary research interests span three areas - neurobehavioral phenotyping and clinical trial outcomes for rare pediatric genetic and metabolic diseases (with special focus on the neuronal ceroid lipofuscinoses/Batten Disease), cognitive function in pediatric hypertension, and psychosocial impacts and improved ascertainment of tic disorders. Dr. Adams is the Co-Director for the Tourette Association of America – New York State Consortium Center of Excellence at the University of Rochester. Current research activities include elucidation of patient-centered outcomes in Batten disease, and development of rigorously defined clinical endpoint measures, characterizing executive dysfunction in pediatric hypertension and potential associations with neuroimaging, and assessment of new screening tools for improved identification of tics and tic disorders. Clinical activities include neuropsychological assessment for a range of conditions, and evidence-based psychosocial interventions for management of Tourette Syndrome/tic disorders and associated conditions.

David Cella studies questions regarding quality of life measurement in clinical trials, cross-cultural equivalence of quality of life measurement, efficacy of psychosocial interventions in chronic illness, and medical outcomes research. He has published more than 700 peer-reviewed articles, most of which focus on the unique contribution that the patient perspective has upon the evaluation of health and health care. Dr. Cella has studied quality of life as a scientific enterprise, bringing the voice of the patient into consideration of value and opportunities for improvement. Dr. Cella developed and is continually refining the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System for outcome evaluation in patients with chronic medical conditions. He was steering committee chair and principal investigator of the statistical coordinating center for the NIH Roadmap Initiative to build a Patient Reported Outcome Measurement Information System (PROMIS®) and is currently the principal investigator of the PRO Core of the Environmental Influences on Child Health Outcomes (ECHO) NIH initiative.
Wen-Hung Chen is currently a reviewer in the Clinical Outcome Assessment Staff in the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), FDA. Dr. Chen’s responsibilities include supporting the review divisions in issues related to the development and interpretation of study endpoints, and supporting the drug development tool qualification program. His areas of expertise include psychometric data analysis and clinical outcome assessments. He was involved with the development of the pain item bank for the NIH leaded patient reported-outcome measurement information system (PROMIS) project. He was also involved in the development of the Exacerbations of Chronic Pulmonary Disease Tool (EXACT) developed under the EXACT-PRO Initiative. Dr. Chen earned his Bachelor’s degree in Science from Chengchi University in Taipei, Taiwan; his Master’s degree and Doctorate in quantitative psychology, with a minor in Biostatistics, from University of North Carolina at Chapel Hill. His publications have appeared in Journal of Educational and Behavioral Statistics, British Journal of Mathematical and Statistical Psychology, Journal of Educational Measurement, Journal of Pain Symptom and Management, Pain, Quality of Life Research, Clinical Drug Investigation, European Respiratory Journal, Chest, and Health Outcomes Research in Medicine.

Gregory Daniel is a Clinical Professor in Duke’s Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center’s pharmaceutical and medical device policy portfolio which includes developing policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. This includes post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform. Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA and Adjunct Associate Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc). Dr. Daniel’s research expertise includes utilizing electronic health data in designing research in health outcomes and pharmacoconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes form the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.

Denise Globe has over 25 years of experience in health care with a focus on quantitative policy research and analysis of RWD assessing the outcomes, process, financing and delivery of care. Over the past 13 years she has focused on economic and outcomes research in industry, leading global access, pricing and reimbursement activities for multiple product launches by developing evidence for US and global health technology assessments. Currently she leads a group of health economic and outcomes researchers focused on US health outcomes research for Novartis oncology and rare disease products. She was an Associate Professor in the Department of Pharmaceutical Economics and Policy for six years focusing on the development and assessment of patient reported outcomes measures and health policy research. Her research has served as a vital resource for policy makers, clinicians, health administrators and researchers in maximizing the health status of both general and specific populations. She also conducted research at
Kaiser Permanente, translating outcomes research into improved care delivery. Her interests and expertise span across the spectrum of policy, academia, industry and practice, in developing novel approaches to many of the challenges in the field of pharmacoeconomic and health policy research.

Chad Gwaltney develops innovative methods to measure patient-centered outcomes in clinical trials. He has published numerous articles and book chapters addressing how the patient’s perspective can be examined to better understand medical product efficacy and safety. He has served on multiple international task forces and US National Institutes of Health review committees and has co-authored best practice guidelines on the development and use of patient-reported outcomes. His academic and industry research includes the design of electronic platforms for the collection of information in real-time in the patient’s natural environment.

Laura Lee Johnson is Deputy Director of FDA CDER’s Division of Biometrics III and the Clinical Outcome Assessment liaison for CDER’s Office of Biostatistics. She provides guidance on design, logistics, implementation, and analysis of research studies ranging from person reported outcome measure qualification to safety and randomized studies of all sizes. Dr. Johnson serves on the FDA-NIH Interagency Clinical Outcome Assessments Working Group and co-directs the NIH Principles and Practice of Clinical Research course. Prior to working at the FDA she spent over a decade at the NIH working on and overseeing clinical research and research support programs. She has been involved with numerous projects developing, validating, and using clinical outcome assessments in both patient care and research. Dr. Johnson received her Ph.D. in Biostatistics from the University of Washington.

Scott Komo is a Senior Statistical Reviewer in the Office of Biostatistics, Center for Drug Evaluation and Research, FDA. He is involved with the design, analysis, and interpretation of studies that use clinical outcome assessments. He is also involved with disease specific guidance development related to study design and analysis. He has supported multiple medical areas since joining the FDA in 1999. He received a BA in Chemistry from the University of California, Davis and an MS and DrPH in Biostatistics from the University of California, Los Angeles.

Tom Permutt supervises the statisticians at FDA working on analgesic, pulmonary, and endocrine drugs. He was among the first to apply methods of causal inference, which he had learned in econometrics, to questions in biostatistics. Tom is topic leader for FDA on the ICH E9(R1) expert working group and co-editor-in-chief of Pharmaceutical Statistics.
Dennis Revicki has more than 30 years’ experience in designing and conducting studies involving health-related quality of life assessment, health services research, psychometrics, and health outcomes research. Dr. Revicki’s primary research interest is in studying health outcomes including applications of health-status assessment and health-utility measures in clinical trials and outcomes research. He has designed and conducted health-related quality of life studies to evaluate outcomes of medical treatment for asthma, chronic hepatitis C, acute and chronic pain, chronic renal disease, various cancers, female and male sexual disorders, gastrointestinal disorders, bipolar disorder, schizophrenia, anxiety disorders, depression, and other chronic diseases. Dr. Revicki completed his graduate work in quantitative psychology at the University of North Carolina at Chapel Hill in 1981. He has directed research and evaluation projects at Evidera, United BioSource Corporation, MEDTAP International, Battelle, Veterans Administration Health Services Research and Development Service, East Carolina University School of Medicine, and the University of North Carolina Department of Psychiatry and School of Education. Dr. Revicki holds faculty appointments in the Department of Health Policy and Administration, University of North Carolina at Chapel Hill; Department of Epidemiology and Health Policy Research, University of Florida; and Department of Psychiatry, Georgetown University Medical Center. Dr. Revicki has over 380 journal publications, and more than 30 book chapters on health status assessment and pharmacoeconomics. In 2005, he edited a book with Dr. William Lenderking on advances in health outcomes research and methods. More recently, he edited a book with Steve Reise titled “Handbook of Item Response Theory Modeling: Applications to Typical Performance Assessment” in 2015. He is a member of the American Pain Society and the International Society for Quality of Life Research. He was formerly the Treasurer and a Member of the Board for the International Society for Quality of Life Research. In 2007, he received the ISOQOL President’s Award for his contributions to health outcomes research.

Johanna H. van der Lee has worked as a clinical epidemiologist at the Pediatric clinical Research Office in the Emma Children’s Hospital AMC Amsterdam since 2003. Her main interests are systematic reviews, clinimetrics, and RCT methodology related to optimal sample sizes. Since July 2009 she has been the convener of the international Standard Development Groups on Data Monitoring Committees and Adequate Sample Sizes of StaR Child Health, a global initiative to improve the quality of research with children (www.starchildhealth.org). From 2011 to 2015 she participated in the EU FP7 funded Global Research in Pediatrics (GRIP) network of excellence (http://www.grip-network.org), and since October 2013 she has been the leader of work package 4(Improved use of patient level information and perspectives) in the Asterix (Advances in Small Trials dESign for Regulatory Innovation and eXcellence) consortium (http://www.asterix-fp7.eu). Next to her methodological work, Hanneke is a member of the Medical Ethics Board of Noord-Holland and of the Data Safety Monitoring Board of the Dutch Association for Obstetrics and Gynaecology.