Workshop on Patient Reported Outcomes (PROs) and Vision-Related Quality of Life (QoL) Questionnaires

Friday, September 29, 2023
10:00 AM – 4:00 PM ET – Virtual Meeting

Biosketches – Organizing Committee
sorted by alphabetically by last name

Name: Emily Chew, M.D.
Institution: National Eye Institute
Background: Dr. Chew is the Director of the Division of Epidemiology and Clinical Applications (DECA), at the National Eye Institute, the National Institutes of Health in Bethesda, Maryland. She is also the Chief of the Clinical Trials Branch in the division. Her research interest includes phase I/II/III clinical trials and epidemiologic studies in retinovascular diseases such as age-related macular degeneration, diabetic retinopathy, and other ocular diseases. She has worked extensively in large multi-centered trials headed by the staff from her division, including the Early Treatment Diabetic Retinopathy Study (ETDRS), the Age-Related Eye Disease Study (AREDS) and the Age-Related Eye Disease Study 2 (AREDS2), which she chairs.

Name: Fraser Bocell, Ph.D.
Institution: US Food and Drug Administration
Background: Dr. Bocell is a Psychometrician and Clinical Outcome Assessment Reviewer with the Patient Science and Engagement Team in CDRH at the FDA. He earned a M.Ed. and Ph.D. in Measurement and Statistics from the University of Washington. At FDA/CDRH he provides expertise and training, as well as develops policy on the evaluation and use of clinical outcome assessments (COAs) in regulatory decision-making. Prior to joining the FDA, he published on the quantitative and qualitative development and evaluation of PROMs, as well as providing statistical expertise to other projects. Dr. Bocell is an expert in psychometric methods and an applied statistician by training, specializing in latent variable models. He continues to explore new methods for developing and evaluating COAs and seeks to improve the relevance and utility of COAs in regulatory decision making.

Name: Todd A. Durham, Ph.D.
Institution: Foundation Fighting Blindness
Background: Dr. Durham is the Senior Vice President, Clinical & Outcomes Research at the Foundation Fighting Blindness, a national non-profit that funds research to treat and cure inherited retinal diseases. He is responsible for directing the Foundation's Clinical Consortium of retinal experts, managing the Foundation's disease registry, developing strategies to enhance product development, partnering with industry, and providing technical input on partnered programs and investment decisions. Dr. Durham earned a BSPH and MS in biostatistics and a Ph.D. in health policy and management (Decision Science and Outcomes Research) from the UNC Gillings School of Global Public Health.

Name: Malvina B. Eydelman, M.D.
Institution: US Food and Drug Administration
Background: Dr. Eydelman is currently the Director of the Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices at the FDA. For over 25 years, as an Expert Medical Officer, Senior Medical Advisor, Director of the Division of Ophthalmic and Ear, Nose and Throat (ENT) Devices, Director of the Division of Ophthalmic, Neurological and ENT Devices, Dr. Eydelman has played a key role in assuring the safety and effectiveness of medical devices. Dr. Eydelman guided development of more than 50 international and national standards, oversaw development of numerous regulations and guidance; and convened over 30 public meetings of FDA Medical Device Committees. She originated numerous symposia and workshops to facilitate device innovation and has been instrumental in expediting development of novel endpoints for clinical trials of pioneering technologies worldwide. DrDr. Eydelman received her M.D. degree from Harvard Medical School and a Doctorate in Health Sciences and Technology from Massachusetts Institute of Technology (M.I.T.). Recently, she was awarded the Advanced Certificate for Executives in Management, Innovation and Technology by M.I.T. Sloan School of Management.

Name: Jason Gerson, Ph.D.
Institution: Patient-Centered Outcomes Research Institute
Background: Dr. Gerson is senior program officer for the Clinical Effectiveness and Decision Science program at the Patient-Centered Outcomes Research Institute (PCORI). He is responsible for providing intellectual and organizational leadership in setting strategic directions, both for the methodological work PCORI funds and the advancement of the science of patient-reported outcomes (PROs); designing and implementing new initiatives to ensure the methodological rigor of the clinical research PCORI funds; and leading PCORI's initiatives on open science, including the development and implementation of a data management and data sharing policy. Dr. Gerson holds a Ph.D. in Health Policy from the Johns Hopkins Bloomberg School of Public Health.

Name: Jimmy T. Le, Sc.D., M.A.
Institution: National Eye Institute
Background: Dr. Jimmy Le is Program Director for Collaborative Clinical Research at the National Eye Institute (NEI), National Institutes of Health. He is responsible for advancing and administering a large program of federally supported, complex, multi-site epidemiologic studies and randomized clinical trials that address eye and vision conditions. Dr. Le is also actively involved with trans-NIH committees and initiatives in his capacity as a Health Scientist Administrator, including the *Transformative Research to Address Health Disparities*, *Community Partnerships to Advance Science for Society*, and *NIH Clinical Trial Operations* initiatives and working groups. Dr. Le received his undergraduate degree in French literature and molecular biology from UC Berkeley; Master's (MA) in International Affairs from the Institute of Political Studies (Sciences Po) in Paris; and Doctor of Science (ScD) in Epidemiology from the Johns Hopkins University Bloomberg School of Public Health.

Name: Flora Lum, M.D.
Institution: American Academy of Ophthalmology
Background: Dr. Lum is the Vice President of Quality and Data Science for the American Academy of Ophthalmology, and the Executive Director of the H. Dunbar Hoskins MD Center for Quality Eye Care. She has overseen the Academy's IRIS® Registry (Intelligent Research in Sight) since its initiation, which has collected 423 million patient visits on over 70 million patients as of July 1, 2023, and reported on quality measures for several thousand ophthalmologists each year since 2017. She oversees the quality of care and evidence-based activities of the Hoskins Center, including Preferred Practice Patterns, Ophthalmic Technology Assessments and Clinical Statements, and the creation, stewardship and revision of performance measures which are incorporated into the Centers for Medicare and Medicaid Services' Merit-based Incentive Payment System. Dr. Lum earned her medical degree from the University of Maryland Medical School and her bachelor's degree from the University of Pennsylvania.

Name: Tieuvi Nguyen, Ph.D.
Institution: US Food and Drug Administration
Background: Dr. Nguyen currently serves as Director of the Division of Ophthalmic Devices (DOD) in FDA's Center for Devices and Radiological Health (CDRH). She received her Ph.D. in Biomedical Engineering. In her role as Director, she oversees the scientific, compliance and regulatory work products related to premarket approval, post-market performance and surveillance, and compliance and enforcement of ophthalmic devices. She also provides scientific and technical leadership and guidance on the development of new regulations and policy issues, including the development of FDA guidance and consensus standard documents.

Name: Michelle Sandrian, Ph.D.
Institution: US Food and Drug Administration
Background: Michelle Gabriele Sandrian is a Biomedical Engineer on the Retinal and Diagnostic Devices Team at the United States Food and Drug Administration (FDA) Center for Devices and Radiological Health. Dr. Sandrian is a lead and consulting Total Product Lifecycle medical device reviewer, who also contributes to the development of FDA guidance documents, public workshops, and international consensus standards. Her technical expertise includes optical coherence tomography imaging, lasers, artificial intelligence-based diagnostic software as a medical device, bioelectronic implants for vision restoration, and electromagnetic compatibility of medical devices. Prior to joining FDA in 2015, Dr. Sandrian was an Assistant Professor in the Departments of Ophthalmology and Bioengineering at the University of Pittsburgh. Dr. Sandrian earned a Doctor of Philosophy in Bioengineering from the University of Pittsburgh Swanson School of Engineering and was a Whitaker Foundation International Postdoctoral Research Scholar at the Medical University of Vienna Center for Medical Physics and Biomedical Engineering (Vienna, Austria).

Name: Michelle E. Tarver, M.D., Ph.D.
Institution: US Food and Drug Administration
Background: Dr. Tarver is an ophthalmologist and epidemiologist, who serves as the Deputy Center Director, Chief Transformation Officer. In this role, Dr. Tarver facilitates the development, implementation, and direction of the Center for Devices and Radiological Health's (CDRH) transformative projects, programs, and initiatives. Under her leadership, CDRH is advancing efforts to include underserved and underrepresented populations in the evaluation of medical devices. She previously served as the Deputy Director of the Office of Strategic Partnerships and Technology Innovation and the Program Director of Patient Science and Engagement. She received a BS in biochemistry from Spelman College and completed the MD/PhD program as well as her residency at the Johns Hopkins University School of Medicine and Bloomberg School of Public Health.

Name: Cheri Wiggs, Ph.D.
Institution: National Eye Institute
Background: Dr. Wiggs serve is a Program Director at the National Eye Institute and now oversees three portfolios: Perception and Psychophysics; Myopia and Refractive Errors; and Low Vision and Blindness Rehabilitation. She represents NEI on many inter-agency and trans-National Institutes of Health (NIH) committees to evaluate research and policy issues, including the Collaborative Research in Computational and Neuroscience Program (with the National Science Foundation and multiple international funding agencies), the NIH Blueprint and BRAIN Initiative Working Groups, the Human Connectome Committee, the Office of Behavioral and Social Sciences Research, the National Center for Medical Rehabilitation Research, and the Office of Extramural Research Basic Experimental Studies in Humans Engagement Committee.