



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 – Speakers and Panelists sorted by order of presentation



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. Dr. Eydelman has organized multi-stakeholder publicprivate partnerships and spearheaded many clinical and laboratory studies designed to improve the safety of medical devices. Dr. 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. Dr. Eydelman has been granted a U.S. patent, published more than 100 peer-reviewed articles, book chapters, and monographs and presented over 200 lectures worldwide.



Name: Michael F. Chiang, M.D. Institution: National Eye Institute

Background: Dr. Chiang is the Director of the National Eye Institute. By background, he is a pediatric ophthalmologist and is also board-certified in clinical informatics. His research focuses on the interface of biomedical informatics and clinical ophthalmology in areas such as retinopathy of prematurity (ROP), telehealth, artificial intelligence, electronic health records, data science, and genotype-phenotype correlation. NEI's mission is to eliminate vision loss and improve quality of life through vision research. NEI supports basic and clinical science programs to develop sight-saving treatments and to broaden opportunities for people with vision impairment of all ages. Dr. Chiang received a BS in Electrical Engineering and Biology from Stanford University, an MD from Harvard Medical School and the Harvard-MIT Division of Health Sciences and Technology, and an MA in Biomedical Informatics from Columbia.



Name: Nakela L. Cook, M.D., M.P.H.

Institution: Patient-Centered Outcomes Research Institute

Background: Dr. Cook is the executive director at the Patient-Centered Outcomes Research Institute (PCORI). PCORI is an independent, nonprofit research organization that seeks to empower patients and others with actionable information about their health and healthcare choices. PCORI funds comparative clinical effectiveness research (CER), which compares two or more medical treatments, services, or health practices to help patients and other stakeholders make better informed decisions. Dr. Cook leads PCORI's research, engagement, dissemination and implementation, and research infrastructure development work. She also provides oversight to a growing number of programs and initiatives designed to create a more efficient, effective, equitable and patient-centered system of health. Dr. Cook earned her medical degree from Harvard Medical School and a Master of Public Health in health care policy and management from Harvard School of Public Health.



Name: Stephen D. McLeod, M.D.

Institution: American Academy of Ophthalmology; UCSF

Background: Dr. McLeod is Chief Executive Officer of the American Academy of Ophthalmology and Professor and Chair Emeritus, Department of Ophthalmology at the University of California, San Francisco. Dr. McLeod is former chair of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee of the U.S. Food and Drug Administration. He has served as a member of the National Advisory Eye Council of the National Institutes of Health, on the Council of the American Ophthalmological Society, and on the Board of Directors of the American Board of Ophthalmology. He pursued his undergraduate degree at Dartmouth College, followed by his medical doctorate degree at the Johns Hopkins University.



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: 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: Ron D. Hays, Ph.D.

Institution: University of California, Los Angeles

Background: Dr. Hays is a UCLA Distinguished Professor of Medicine at the University of California, Los Angeles, and affiliated adjunct researcher at the RAND Corporation who specializes in patient-reported measurement development and evaluation. He was an Associate Editor from 1991-2001 and Editor-in-Chief from 2005-2009 for the *Quality of Life Research* journal, and Co-Editor-in-Chief from 2020-2022 for the *Journal of Patient-Reported Outcomes*.



Name: Robert Finger, M.D., Ph.D.

Institution: University Hospital Mannheim

Background: Dr. Finger is Director of the Department of Ophthalmology at University Hospital Mannheim and Professor of Ophthalmology at the University of Heidelberg. His research is focused on assessing risk factors for the development and progression of age-related macular degeneration and other retinal diseases, treatment outcomes (patient and physician reported) and the development of novel outcome measures, including structural, functional and patient-reported assessments, all with a focus on retinal diseases. For this he applies epidemiological as well as clinical research methodology including qualitative research methods related to the development of patient reported outcomes as well as for patient participation. He collaborates closely with AI experts to develop automated image analysis solutions applicable to research questions in ophthalmic epidemiology.



Name: Judith E. Goldstein, O.D. Institution: Johns Hopkins University

Background: Dr. Goldstein is the Director of the Lions Vision Research and Rehabilitation Center and an Associate Professor of Ophthalmology and Rehabilitation Medicine at the Wilmer Eye Institute at The Johns Hopkins School of Medicine. In addition to leading the clinical and teaching program, Dr. Goldstein's research focuses on measurement of low vision rehabilitation outcomes and the calibration of visual function questionnaires to enable comparative estimates. Her current work focuses on improving health services delivery to the growing population in need in the US. Dr. Goldstein received her Doctor of Optometry from the State University of New York College of Optometry and completed residency training at the Baltimore Veterans Administration Medical Center.



Name: Emily Grattan, Ph.D.

Institution: University of Pittsburgh

Background: Dr. Grattan is an assistant professor in the Department of Occupational Therapy and research health scientist with the Veterans Affairs Pittsburgh Healthcare System. Her current research program focuses on improving measurement and treatment of visual and perceptual impairments post stroke. She also collaborates with investigators in the Department of Ophthalmology to advance low vision rehabilitation. Dr. Grattan received her BS in health sciences and MS in occupational therapy from Duquesne University, her PhD in rehabilitation science from the University of Pittsburgh.



Name: Pradeep Ramulu, M.D., Ph.D. **Institution:** Johns Hopkins University

Background: Dr. Ramulu is Professor of Ophthalmology and the director of the Wilmer Eye Institute glaucoma division. He specializes in caring for both routine and complex glaucomas, including glaucomas requiring repeat operations, glaucoma occurring in the context of corneal or retinal disease and glaucoma occurring in newborns and young children. Dr. Ramulu's research focuses primarily on how glaucoma affects the individual. Specifically, he has studied the types of difficulties that glaucoma patients experience with regards to reading, walking, falling, driving and traveling outside the home. He received his MD and PhD from the Johns Hopkins University.



Name: Carol L. Shields, M.D. Institution: Wills Eye Hospital

Background: Dr. Shields is Chief of the Ocular Oncology Service at Wills Eye Hospital and Professor of Ophthalmology at Thomas Jefferson University in Philadelphia, Pennsylvania. Dr. Shields is a member of numerous ocular oncology, pathology, and retina societies and serves on the editorial board of several peerreviewed journals. She completed her ophthalmology training at Wills Eye and subsequently did fellowship training in ocular oncology, oculoplastic surgery, and ophthalmic pathology.



Name: Kuldev Singh, M.D. Institution: Stanford University

Background: Dr. Singh is Professor of Ophthalmology and Director of the Glaucoma Service. Dr. Singh's current academic interests include glaucoma and cataract surgery, the epidemiology of myopia and glaucoma, ophthalmic genetics, as well as health care delivery in underserved communities. He is an investigator in the National Institutes of Health funded NEI Glaucoma Human Genetics Collaboration and is funded by the U.S. Food and Drug Administration (FDA) to study patient related outcomes with minimally invasive glaucoma surgery. Dr. Singh received his MD and MPH degrees from the Johns Hopkins University and was a Dana Foundation Fellow at the Wilmer Eye Institute. He completed ophthalmology residency training at Casey Eye Institute (OHSU) and a clinical glaucoma fellowship at the Bascom Palmer Eye Institute.



Name: S. Robert Levine, M.D.

Institution: Mary Tyler Moore Vision Initiative

Background: Along with his wife, Mary Tyler Moore, Dr. Levine helped JDRF (www.idrf.org) grow to become the leading type 1 diabetes research funding and advocacy non-profit in the world. To help make his wife's dream of a world without vision loss from diabetes come true, Dr. Levine has conceived, organized, and leads the Mary Tyler Moore Vision Initiative (www.marytylermoore.org), a global cross-sector collaborative dedicated to bridging barriers to progress and accelerating the development of new ways to preserve and restore visual function in people at risk for and with vision loss due to diabetic retinal disease. The Mary Tyler Moore Vision Initiative is hosted by the University of Michigan's Caswell Diabetes Institute and Kellogg Eye Center.



Name: Alessio, Andrea and Fabio

Background: Alessio is a 5th grader in Pittsburgh Public Schools. He likes playing soccer and basketball, reading books he shouldn't be reading, and playing video games. Andrea is a substitute teacher. She prefers working with the littlest ones, and she enjoys working out almost daily. Fabio is an MD/PhD, and works in the Department of Psychiatry at the University of Pittsburgh. He grew up in Italy and enjoys playing the piano, when he has spare time.



Name: Barbara

Background: Barbara is a graphic designer, fine artist, jewelry designer, and editor. Her patient advocacy began in 2001, following a disastrous LASIK surgery. As a contributor to the former Surgical Eyes bulletin board, she was moved by the stories posted to work toward rehab options for patients with similar issues. In 2004, the nonprofit Vision Surgery Rehab Network opened with co-founder David Hartzok, OD, and In 2009, the FDA recruited her as a patient representative, a role in which she served on the PROWL study. In addition to LASIK-related issues, she has served as patient representative on numerous other FDA advisory committee panels on various topics with which she has personal experience. Currently self-employed, she is recovering from a July 2023 4-level lumbar spinal fusion, complete with hardware into the thoracic spine.



Name: Jaime

Background: Jaime is a Magistrate for the Department of Magistrate Services with the Virginia Court System for the past 5 years. She has spent her career working within the Virginia Courts for 15 years. She holds a bachelor's degree in Sociology from Mary Baldwin University. Jaime is diagnosed with Retinitis Pigmentosa with comorbidities of cystic macular edema, a lamellar macular hole and a cataract. She participated in a research protocol for minocycline with NIH/NEI and since has remained as in the NIH/NEI genetic protocol. She lives in the Shenandoah Valley, Virginia with her husband, 11-year-old daughter and 2 dogs.



Name: John

Background: John is a now retired US Air Force officer. He graduated from Atlantic Christian College with a BA in Political Science/History and Wake Forest University School of Law with a JD, specializing in Contract Law. John has served oversees (Thailand, Japan, Taiwan, Philippines, New Zealand, South Korea, Okinawa, Guam) and in the US (Denver CO, Las Vegas NV, San Antonio TX, Dayton OH and Washington D.C.). During his last 5 years in the US Air Force, John served as advisor to the Secretary of the Air Force on contracts of interest to the US House of Representatives and the Senate (hearings, testimonies, briefings, etc). John also has a civilian career, serving as in-house counsel, registered lobbyist and director of Government Affairs for the National Tooling & Machining Association (NTMA) representing 3,200 manufacturing companies throughout the U.S. John retired from the NTMA after he was no longer able to drive due to AMD. He is currently a Senior Guide (volunteer) for the US Capitol Historical Society, providing tours and lectures on the history of the Capitol Building and legislative process. He also taught English as a second language; co-chairs the Visually Impaired Persons support group (Vienna, VA); is a member of the Visually Impaired Support Group (Reston, VA), Library Access Committee (Fairfax County, VA); and volunteers for various projects with the National Eye Institute and US FDA.



Name: Judy

Background: Judy is a seasoned entrepreneur with over 24 years of international business expertise, specializing in the Asian market. Judy's journey as a first-generation immigrant from China, coupled with her education at Boston College and MBA programs at CEIBS in Beijing, exemplifies her drive for continuous learning and growth. She is the founder of the 889 Global Solutions Fund and the Judy Huang Scholarship at The Columbus Foundation to support students who are Asian and in financial need and demonstrate perseverance and hard work. Judy resides in Columbus, Ohio. She has been living with glaucoma for about 16 years. Judy has had several surgeries for glaucoma and has been involved in at least one clinical trial at Stanford University. She has been a donor to Glaucoma Research Foundation for many years, and now serves on its Development Committee.



Name: Kendra Hileman, Ph.D.

Institution: Alcon

Background: Dr. Hileman is Vice President, Head of Instrumentation R&D at Alcon, here she leads the engineering teams responsible for development of optometric, cataract, refractive, and vitreoretinal surgical and diagnostic equipment. Prior to that position, she was Vice President, Head of Clinical Research & Development at Alcon. In this role, she had responsibility for the design and execution of clinical studies to support global regulatory and post-market studies. She led all functions of clinical research including clinical project leadership, global medical affairs, biostatistics, data management, statistical programming, medical writing, and clinical study public disclosure. She received her PhD from The University of Texas at Arlington.



Name: Mark Humayun, M.D., Ph.D.

Institution: University of Southern California

Background: Mark S. Humayun, MD., PhD., is the Cornelius J. Pings Chair in Biomedical Sciences, Professor of Ophthalmology, Biomedical Engineering, and Integrative Anatomical Sciences, Director of the USC Ginsburg Institute for Biomedical Therapeutics, and Co-Director of the USC Roski Eye Institute. Dr. Humayun is an internationally recognized pioneer in vision restoration. He assembled a team of multidisciplinary experts to develop the first FDA approved artificial retina, Argus II, for sight restoration. He has more than 140 issued patents and over 300 peer reviewed publications. He has a google scholar H index of 105.



Name: Steven Schallhorn, M.D. Institution: ZEISS Meditec; UCSF

Background: Dr. is board certified and licensed ophthalmologist in private practice in San Diego, CA, Chief Medical Officer for ZEISS Meditec, Clinical Professor of Ophthalmology at the University of California, San Francisco and Chairman of the Optical Express Medical Advisor Board. After graduating from Colorado State University, Dr Schallhorn entered the US Navy in 1977 and was trained as an F-14 naval aviator. Following several deployments on USS Ranger, he was selected and served as a Navy Fighter Weapons School instructor (TOPGUN) teaching air combat to fleet fighter pilots. He then completed a medical degree at the Uniformed Services University of the Health Sciences, ophthalmology residency at the Naval Medical Center San Diego in 1993, and cornea fellowship at the Doheny Eye Institute, University of Southern California. He retired from the Navy in February 2007 as the US Navy's Refractive Surgery Program Manager where he managed a multi-million dollar budget and directed the center at the Naval Medical Center San Diego. He was the founder of the Department of Defense refractive surgery program which now consists of over 20 centers providing mission-enhancing surgery to active duty personnel.



Name: Beverly Weidmer, M.A. Institution: RAND Corporation

Background: Beverly Weidmer is a Senior Survey Director in the RAND Survey Research Group (SRG). She has 30+ years of experience in both quantitative and qualitative research methods, including all aspects of survey design and management, instrument development, focus groups, and methods for assessing the validity of survey instruments, including cognitive interviews and usability testing. She has expertise in translation, in the design and testing of culturally appropriate survey instruments, in strategies to maximize response rates, and in reducing sample attrition and item non-response. She specializes in the design and implementation of complex field projects including longitudinal surveys, multi-mode data collection, and surveying special populations including immigrants, low literate populations, welfare recipients, the elderly, and children and adolescents. In her career at RAND Ms. Weidmer has managed surveys at both the local and national level including large-scale panel surveys of Medicare and Medicaid beneficiaries, panel surveys of health care providers, and panel surveys of children involving the collection of anthropometric measurements, biomarkers, and measures of child development. Ms. Weidmer is also experienced in conducting crosscultural research outside the U.S. including projects in Mexico, Guatemala, the former Yugoslavian Republic of Macedonia, Indonesia, Thailand, and Vietnam. Ms. Weidmer was born and reared in Mexico and is completely bilingual and bi-cultural.



Name: Carol M. Mangione, M.D.

Institution: University of California, Los Angeles

Background: Dr. Mangione is chief of the Division of General Internal Medicine and Health Services Research and the Barbara A. Levey, MD, and Gerald S. Levey, MD, endowed chair in medicine at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA) and Department of Medicine Executive Vice Chair for Health Equity and Health Services Research. Dr. Mangione is the immediate past chair of the U.S. Preventive Services Task Force. Dr. Mangione received her B.S. from the University of Michigan, Ann Arbor; her M.D. at the University of California, San Francisco; and her M.S.P.H. from the Harvard School of Public Health and has completed fellowships at Harvard Medical School.



Name: Paul P. Lee, M.D., J.D. Institution: University of Michigan

Background: Dr. Lee is the executive director for the University of Michigan (U-M) Medical Group and senior associate dean for clinical affairs in the U-M Medical School. Dr. Lee is also a professor in the Department of Ophthalmology and Visual Sciences. He has been principal investigator on research projects to evaluate the appropriateness of cataract surgery, the quality of glaucoma and diabetic retinopathy care, utilization patterns of eye care, provider workforce analyses for ophthalmology and orthopedics, and analyses of failure patterns for the treatment of diabetes related eye disease and glaucoma. Dr. Lee received his law degree from Columbia University in 1986. He received his medical degree from the University of Michigan that same year.



Name: R.J. Wirth, Ph.D.

Institution: Vector Pscyhometric Group, LLC

Background: Dr. Wirth is Chief Executive Officer, co-Founder, and a managing partner at VPG. Dr. Wirth received his PhD in quantitative psychology / psychometrics from the historic LL Thurstone Psychometric Laboratory at University of North Carolina – Chapel Hill. Prior to leading VPG, Dr. Wirth held research positions at the Frank Porter Graham Child Development Institute at The University of North Carolina and in the School of Medicine at the University of Washington. For more than a decade, Dr. Wirth has collaborated widely within the pharmaceutical and medical device industries to develop and/or evaluate the measurement properties of clinical outcome assessments and was awarded (as co-PI) one of the first FDA-funded CDER pilot program grants: Standard core clinical outcome assessments and their related endpoints.



Name: Cheryl D. Coon, Ph.D. Institution: Critical Path Institute

Background: Cheryl D. Coon, PhD, is Vice President of the Clinical Outcome Assessment (COA) Program at Critical Path Institute (C-Path). Dr. Coon is a psychometrician with two decades of experience developing and evaluating COAs for use in constructing patient-centered endpoints. Her experience includes the statistical analysis of COA endpoint data and the communication of psychometric and efficacy evidence to regulatory authorities and other stakeholders. Dr. Coon is a recognized thought-leader in the field of COAs and seeks to generate evidence that allows the benefits of new therapies to be clearly communicated to patients and clinicians for informing treatment decisions. Dr. Coon received her PhD in Quantitative Psychology from the University of North Carolina at Chapel Hill, during which time her research focused on item response theory and included early work on the Patient-Reported Outcomes Measurement Information System.



Name: Rikki Mangrum, M.L.S.

Institution: Vector Pscyhometric Group, LLC

Background: Rikki Mangrum, MLS, is Director of Patient Centered Research at Vector Psychometric Group, LLC (VPG) and has conducted literature reviews and qualitative research in health for 17 years. She has interviewed hundreds of patients, caregivers, and stakeholders and has evaluated both patient-reported outcome measures and healthcare quality indicators. She has authored dozens of peer-reviewed articles and is a frequent speaker on qualitative methods for developing and evaluating measures. She has served on the Centers for Medicare & Medicaid Services' Measure Applications Partnership advisory group for post-acute and long-term care, and is a senior editor for the journal The Qualitative Report.



Name: Lori McLeod, Ph.D.
Institution: RTI Health Solutions

Background: Dr. McLeod is Vice President of Patient-Centered Outcomes Assessment at RTI-HS and a psychometrician with more than 20 years of measurement experience, including expertise in instrument development and validation, as well as experience supporting the regulatory review of clinical outcome assessments. Dr. McLeod has expertise in classical and modern psychometric methods such as factor analysis, Rasch analysis, and item response theory. In addition, Dr. McLeod has experience conducting and analyzing data from clinical trials and observational studies, including data to document burden of disease and treatment benefit. Dr. McLeod also serves as an adjunct faculty in the Department of Health Policy and Management at the University of North Carolina at Chapel Hill.



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: 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 the University of California, 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: Emily Y. 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.