Cochlear Implant Innovation, Research and Advancement (CIRCA)

Virtual Workshop

February 1 -2, 2022

Co-Sponsored by U.S. Food and Drug Administration Center for Devices and Radiologic Health (CDRH) and Medical Device Epidemiology Network (MDEpiNet)

MEETING CO-CHAIRS

Nilsa Loyo-Berríos, PhD, MSc
Acting Associate Director for the Office of Health Technologies 1 (OHT1)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration

Veronica Sansing-Foster, PhD, MS
Senior Epidemiologist, Office of Clinical Evidence and Analysis (OCEA)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration

Goal	The goal of this workshop is for stakeholders to gain a better understanding of the current landscape of cochlear implants and their related regulatory processes, and to contribute best practices to strengthen the research and clinical infrastructure to capture and assess patients' experiences with cochlear implants. This workshop will give stakeholders an opportunity to provide input on the challenges and opportunities for advancing cochlear implant research and innovation.
Objectives	(1) Explore current science and the clinical practice as it relates to the future directions of cochlear implants technology development. (2) Identify critical research areas and review various clinical data types (e.g., data collected from pivotal studies, real world data, registry data, etc.) that could support assessment of device performance, new device indications, and device innovation. (3) Discuss minimum core data elements (MCDE) that would efficiently capture the experience of patients undergoing cochlear implant procedures. (4) Summarize workshop consensus in a future journal article.

Meeting Agenda

DAY 1
February
1st

Cochlear Implant Innovation, Research and Advancement (CIRCA)

TIME	TOPIC	PRESENTER
8:30am-8:45am	**Welcome and Introductory Remarks**	MC: Veronica Sansing-Foster, *FDA* Malvina Eydelman, *FDA* Vasum Peiris, *FDA*
8:45am-10:18am	**Session I: Cochlear Implants Technology and Regulation**	
8:45am-9:00am	Cochlear Implants Regulatory History and Challenges, FDA Perspective	Nandu Nandkumar, *FDA*
9:00am-9:20am	Cochlear Implants Technological Developments, Industry Perspective	Jason Galster, *Advanced Bionics* Laura Blair, *Cochlear Americas* Ilona Anderson, *Med-El* Eric Pepin Lehalleur, *Neurelec (Oticon)*
9:20am-9:35am	Hearing Loss and Cochlear Implants Patients' Perspective: Adults & Pediatrics	Donna Sorkin, *American Cochlear Implant Alliance* Barbara Mellert, *Patient Parent Representative*
9:35am-9:50am	Clinical Perspectives on Cochlear Implants, Academia/Clinical Perspective	Marlan Hansen, *University of Iowa Hospitals and Clinics*
9:50am-9:58am	Payer's Perspective: Blue Cross Blue Shield	Lawrence Simon, *BCBSLA*
9:58am-10:18am	***Moderators:*** Eric Mann, *FDA* Nicholas Reed, *John Hopkins University*	
10:18am-10:28am	**Break**	
10:28am-12:58pm	**Session II: Evaluation of Cochlear Implants Throughout the Total Product Life Cycle**	
10:28am-10:43am	Evidence Needs for Patients Candidacy Criteria	Terry Zwolan, *Hearing First* Meredith Holcomb, *University of Miami (FL)*
10:43am-11:13am	Considerations for Preservation of Residual Hearing and Electroacoustic Stimulation	Bruce Gantz, *University of Iowa Carver College of Medicine*

		Craig Buchman, *Washington School of Medicine, St. Louis*
11:13am-11:28am	Evidence Needs and Considerations for Individual Ear Indications	Oliver Adunka, *Ohio State University*
11:28am-11:43am	Evidence Needs and Considerations for Pediatric Patients	Nancy Young, Lurie *Children's Hospital*
11:43am-11:58am	Evidence Needs for Post-Approval Studies Required as Condition of Approval for Cochlear Implants	Ting Zhang, *FDA*
11:58am-12:13pm	Disparities in Access to Cochlear Implants	Anand Devaiah, *Boston Medical Center* Matthew Bush, *University of KY College of Medicine*
12:13pm-12:58pm	***Moderators:*** René Gifford, *Vanderbilt University* Jennifer Deal, *Johns Hopkins*	
12:58pm-1:43pm	**Lunch Break**	
1:43pm-3:58pm	**Session III: Evidence Needs to Support Cochlear Implants Innovation**	
1:43pm-1:58pm	Emerging Cochlear Implant Technologies and Associated Evidence Needs	Matthew Carlson, *Mayo Clinic*
1:58pm-2:13pm	Alignment of the Regulatory and Reimbursement Systems: Impact on the Cochlear Implants Community	Terry Zwolan, *Hearing First*
2:13pm-2:28pm	Real-World Evidence for Regulatory Purposes: Needs and Opportunities	Veronica Sansing-Foster, *FDA* Nilsa Loyo-Berríos, *FDA*
2:28pm-2:58pm	Digital Health Opportunities for Innovation	Anindita Saha, *FDA* John Hansen, *Erik Jonsson School*
2:58pm-3:13pm	Capabilities Patient Reported Outcome Measures	Richard Gliklich, *Reg-ent* Theodore McRackan, *University of South Carolina*
3:13pm-3:58pm	***Moderators:*** Anand Devaiah, *Boston Medical Center* Nandu Nandkumar, *FDA*	
3:58pm-4:08pm	**Day 1 Concluding Remarks**	**Art Sedrakyan, *WCM***

DAY 2
February 2nd

Cochlear Implant Innovation, Research and Advancement (CIRCA)

TIME	TOPIC	PRESENTER
8:30am-8:45am	**Welcome and Goals for the Day**	MC: Nilsa Loyo-Berríos, *FDA* Daniel Caños, *FDA* Art Sedrakyan, *WCM*
8:45am-10:30am	**Session IV: Working on Data Infrastructure**	
8:45am-9:00am	NESTcc Overview	Sandra Siami, *MDIC/NESTcc*
9:00am-9:15am	Coordinated Registries Networks (CRN) as Foundation for Device Evaluation	Art Sedrakyan, *WCM*
9:15am-9:30am	Overview of Cochlear Implant Registries	Richard Gliklich, *Reg-ent* Jed Grisel, *Texoma ENT*
9:30am-9:45am	The Delphi Process: Stakeholders Effort to Identify Minimum Core Data Elements (MCDE) for Cochlear Implants	Suvekshya Aryal, *WCM* Martha Velezis, *FDA*
9:45am-10:30am	***Moderators:*** Shu-Chen Peng, *FDA* James C. Denneny, *American Academy of Otolaryngology*	
10:30am-10:40am	**Break**	
10:40am-12:20pm	**Session V: Tailoring Methods to Data Infrastructure**	
10:40am-10:55am	Lessons Learned from the Implementation of MCDE	Vahan Simonyan, *MDEpiNet*
10:55am-11:10am	International Registries - Blueprint for Success	Christian-Alexander Behrendt, (*ICVR)/Germany*
11:10am-11:25am	Implementation of MCDE across the Coordinated Registry Network (CRN) ecosystem	Martha Velezis, *FDA*
11:25am-11:35am	Future Application of RWE/RWD for Hearing Devices	Lindsay DeVries, *FDA*
11:35am-12:20pm	***Moderators:*** Danica Marinac-Dabic, *FDA* Art Sedrakyan, *WCM*	
12:20pm-12:35pm	**Concluding Remarks:** **Next Steps and Adjournment**	Anand Devaiah, *Boston Medical Center* Danica Marinac-Dabic, *FDA*

Speaker Biographies

Oliver F. Adunka, MD, FACS (Workshop Committee Member) is the William H. Saunders MD Endowed Professor and the Vice Chair for Clinical Operations in the Department of Otolaryngology, Head & Neck Surgery at The Ohio State University. He also serves as the Director of the Division of Otology, Neurotology, and Cranial Base Surgery within the department. Further, he is the Director of Pediatric Otology & the Hearing Program at Nationwide Children's Hospital, one of the largest institutions of its kind in the United States. Dr. Adunka is a native of Vienna, Austria. He earned his medical degree from the University of Vienna Medical School in Austria. He completed his otolaryngology residency training in Vienna, Austria and at the Johann Wolfgang Goethe University in Frankfurt am Main, Germany. He subsequently subspecialized in otology, neurotology and lateral skull base surgery at the University of North Carolina in Chapel Hill. Before accepting his current position at The Ohio State University, Dr. Adunka practiced at UNC serving most recently as an Associate Professor in the Department of Otolaryngology, Head & Neck Surgery. His clinical practice includes all aspects of otology, neurotology, and lateral skull base surgery but especially cochlear implantation and complex posterior as well as middle fossa skull base surgery for sporadic disease as well as for Neurofibromatosis Type II. Dr. Adunka is a NIH funded clinician scientist; current and past research has focused on various aspects of cochlear implantation including clinical and experimental research on electrode insertion trauma, hearing preservation, and combined electric acoustic stimulation. He has a special interest in real-time monitoring during electrode insertion to improve future generations of cochlear implants. His lab has lead the development of electrocochleography in cochlear implantation, a new technology that has recently been implemented in commercial cochlear implant systems.

Ilona Anderson, PhD trained as an Audiologist and Speech Language Pathologist at the University of Witwatersrand, Johannesburg, South Africa. She completed her Doctorate in Medical Science at the University of Antwerp, Antwerp, Belgium. She initially worked in various private practices in Johannesburg. Following this, she worked as a clinical tutor and lecturer at the University of Witwatersrand, where she also worked on the Johannesburg Cochlear Implant Programme. In 2001, Ilona joined MED-EL Innsbruck as a Clinical Research Specialist. She is currently the Corporate Director of Clinical Research at MED-EL. Her team runs pre-market and post-market studies, they also conduct clinical evaluations for updates and recertifications, and support journal writing activities. Ilona an author on over 47 papers.

Suvekshya Aryal, MPH (Workshop Committee Member) is a health care professional with experience in epidemiology, health policy and outcomes research in public health. She holds a Master of Public Health in Epidemiology from Columbia University Mailman School of Public Health in New York and a Bachelor of Science in Biology from Salem College in North Carolina. She is trained in quantitative and qualitative research and analysis, and database management. Aryal is currently works as a Senior Research Analyst at the Weill Cornell Medicine at the Department of Population Health Services and serves as a Program Manager for the Medical Device Epidemiology MDEpiNet Coordinating Center.

Laura Blair began her professional career as a Clinical Audiologist working in the Cochlear Implant Program at the Mayo Clinic in Rochester, Minnesota. Seeing the impact of cochlear implants led her to accept a role with Cochlear Americas in 2005. Since joining Cochlear, Laura has held roles in sales and marketing before pivoting in 2011 for an opportunity in Regulatory Affairs. Laura has been the Director of Regulatory Affairs for Cochlear Americas since 2017 and has an accomplished track record working with the FDA and other regulatory bodies to achieve successes for a number of Class II and Class III medical devices. Laura has a Doctorate in Audiology from the University of Florida, an MA from the University of Minnesota, and BS from Univ. of Wisconsin-Madison.

Christian-Alexander Behrendt, MD, FESVS is senior consultant vascular and endovascular surgeon and senior clinical lecturer in vascular surgery. He is fellow member of the European Society for Vascular Surgery (ESVS) and elected international member of the Society of Vascular Surgery (SVS). Christian is head of the research group GermanVasc (www.germanvasc.de) and deputy clinic director at the University Medical Centre Hamburg-Eppendorf (UKE), Department of Vascular Medicine, Hamburg, Germany. His main field in clinical care is lower extremity peripheral artery disease (PAD). He has published more than 170 peer-reviewed original contributions and reviews (more than 50 of them as first or last author in highly-ranked scientific journals, 1st quartile in surgery, h-index >22). His research group GermanVasc currently employs four full time scientists and experienced statisticians. Between 2014 and 2020, Christian became an expert in real-world-evidence research using health insurance claims data and registries for vascular research and quality improvement. His main field of interest in research are health services research, real-world-evidence, medical device research, big data, and comparative outcome research. Christian is current chairman of the VASCUNET collaboration, a cross-border network comprising 28 national and international quality improvement registries in vascular medicine. He is founding member of the International Consortium of Vascular Registries (ICVR) and the Medical Device Epidemiology Network (MDEpiNet), where he serves as chairman and executive director of the German chapter. Christian is

principal investigator of numerous prior and ongoing registry studies in Germany (PSI-Registry, EQS-Registry, L-ACMAG, CORONA, IDOMENEO, RABATT). He is currently leading two large multistage multimethodological projects on the treatment of PAD in Germany (IDOMENEO, 01VSF16008, ClinicalTrials.gov NCT03098290 and RABATT, 01VSF18035). As a member of the scientific steering committee and co-spokesman of the research council of the Hamburg City Health Study (HCHS), he is involved in the largest population-based epidemiological cohort study on chronic diseases.

Craig Buchman, MD is the Lindburg Professor and Head, Department of Otolaryngology-Head and Neck Surgery at Washington University in St. Louis. After a surgical internship, he took a research fellowship and residency at the University of Pittsburgh. He completed a fellowship in neurotology at the House Ear Clinic in Los Angeles. Dr. Buchman's interests spans neurotology. He has lectured world-wide on cochlear implantation, electroacoustic stimulation, auditory neuropathy, and auditory brainstem implantation. He currently chairs the William House Cochlear Implant Study Group and is the immediate past chair of the Joint Committee on Infant Hearing (JCIH). He is past Chair of the Implantable Devices Committee of the AAO-HNS and a Founding Board Member and Chair of the American Cochlear Implant Alliance (ACIA). He has received numerous awards including the *Harris P. Mosher Award* from the Triological Society and was elected to the CORLAS. He currently serves as the President of the American Neurotology Society (ANS). His research program includes clinical trials investigating cochlear implantation, auditory electrophysiology, and auditory brainstem implants. His work has been supported by major grants from the National Institutes of Health (NIH) and the Department of Defense (DoD), as well as private foundations and industry partners. He holds a number of U.S., European and Canadian patents and has published more than 180 peer-reviewed manuscripts.

Matthew L. Bush, M.D., Ph.D., MBA, FACS is the Vice Chair for Research and a Professor in the Department of Otolaryngology – Head and Neck Surgery at the University of Kentucky in Lexington, Kentucky. He earned his M.D. degree at Marshall University in Huntington, WV. He completed Otolaryngology residency at the University of Kentucky followed by a post-doctoral research fellowship and Neurotology & Cranial Base Surgery fellowship at The Ohio State University. He completed his PhD and his MBA at the University of Kentucky. His research is focused on hearing healthcare disparities. He serves as the PI of several NIH-funded community-based trials (U01OD033247, R01DC017770, R21DC019602) to promote hearing healthcare access and utilization among underserved populations.

Daniel Arthur Caños, PhD, MPH is the Director of the Office of Clinical Evidence and Analysis (OCEA) in the FDA Center for Devices and Radiological Health (CDRH). Prior to joining OCEA in 2019, Daniel was the Director of the Evidence Development Division (EDD) in the Centers for Medicare and Medicaid Services (CMS) Coverage and Analysis Group (CAG) and was on a part time detail within the FDA CDRH. The EDD work included National Coverage Analyses (NCAs) and National Coverage Determinations (NCDs) involving Coverage with Evidence Development and review of FDA approved Investigational Device Exemption studies for CMS coverage determination. Before joining CAG in 2016, Daniel was an Associate Director in the FDA CDRH Division of Epidemiology. He originally joined FDA in 2008. He received a BA in Psychology from the University of Cincinnati, MPH from the George Washington University, and PhD in Epidemiology from the University of North Carolina at Chapel Hill, NC.

Matthew Carlson, MD is a Professor of Otolaryngology and Neurosurgery at the Mayo Clinic, in Rochester, Minnesota. He is currently the cochlear implant program medical director, neurotology fellowship program director, and division chair of neurotology at Mayo Clinic. Dr. Carlson serves as the site director for Headmirror.com, an independent non-profit open access educational resource for otolaryngology trainees and practicing physicians and is the co-chair of the Hearing Health Collaborative, dedicated to overcoming the challenges in advancing good healthcare practices and public policy on hearing care. He has authored over 370 peer-reviewed publications, 40 book chapters, and has served as an editor on 5 textbooks. Dr. Carlson's primary clinical and research interests surround cochlear implant and vestibular schwannoma care and outcomes. He also devotes significant time to educational content development.

Jennifer A. Deal, PhD is an epidemiologist and gerontologist with expertise in hearing loss and cognitive aging. She is an Assistant Professor of Epidemiology and Otolaryngology-Head & Neck Surgery at the Johns Hopkins University, and Associate Director for Academic Training with the Johns Hopkins Cochlear Center for Hearing and Public Health. Dr. Deal studies how hearing loss impacts the aging brain to understand pathways involved and to inform development of public health prevention strategies.

James C. Denneny III, MD (Workshop Committee Member) is the Executive Vice President/CEO of the American Academy of Otolaryngology—Head and Neck Surgery and its Foundation (AAO-HNS/F), one of the oldest medical associations in the United States. The Academy represents about 13,000 otolaryngologist—head and neck surgeons who treat the ear, nose, throat, and related structures of the head and neck. He is a past president of the AAO-HNS/F, with 17 years of service on the Boards of Directors and 22 years on the Board of Governors, including a term as chairman. Dr. Denneny has held leadership positions in many partnerships, coalitions, and workgroups such as the Academy's Physician Payment Policy Workgroup and the Ad Hoc Payment Model Workgroup. He was also the Academy's Coordinator for Socioeconomic Affairs on two occasions. His career has spanned both private and academic practice. Before serving the Knoxville, TN, community for 24 years as a private practitioner, he held academic appointments in Houston and Indianapolis. In 2011, he left private practice to join the Department of Otolaryngology—Head and Neck Surgery at the University of Missouri, where he remains Adjunct Professor of Clinical Otolaryngology. He is part-time at Johns Hopkins School of Medicine as an Adjunct Professor. He assumed his current role as Executive Vice President/CEO in December 2014. Dr. Denneny received a Bachelor of Science from Baylor University in Waco, TX. He earned his medical degree and finished a general surgery internship at the University of Oklahoma Medical School. He completed his residency in otolaryngology-head and neck surgery at the University of Pennsylvania School of Medicine in Philadelphia, PA, with a subsequent fellowship in facial plastic reconstructive surgery at the University of Illinois in Chicago, IL with M. Eugene Tardy, MD. He is a fellow of the American College of Surgeons (ACS), has served as Secretary of the ACS Board of Governors and is a member of the ACS Board of Regents. During his term as president of the organization, the first Diversity and Inclusion Committee was formed in 2009 and the first Chair, Duane Taylor, MD, has become the first African American president of the organization. During his six-year tenure as EVP/CEO, four of the five women presidents in the Foundation's history have been elected. Dr. Denneny has a specific interest in investigating social determinants of health through the clinical data registry established several years ago. He is also initiated a campaign to educate and recruit medical students from underrepresented minorities into the specialty.

Anand K. Devaiah, MD, FACS, (Workshop Committee Member) is a Professor in the Departments of Otolaryngology, Neurological Surgery, and Ophthalmology at Boston University. His work bridges the worlds of development and implementation, leading and facilitating collaborations focused on improving value in the health care system through technological innovations. Dr. Devaiah's experience spans technology development, evaluation, implementation, research, administration, and regulatory pathways. He has worked closely with companies -- from startups to established enterprises – in different ways including team-based product development, building core business strategies, marketing strategies, corporate governance, developing expanded use cases for existing technology, and as an investor. This includes health care and non-health care technologies. He has also served as a Medical Officer/Fellow with the Food and Drug Administration in the Center for Devices and Radiologic Health as a part of the Ear, Nose, and Throat Branch from 2015-2017. He was then named the

inaugural Director of the Biomedical & Health Technology Development & Transfer Domain in the Boston University Institute for Health System Innovation & Policy (IHSIP) and remained in this position until conclusion of the IHSIP Charter at the end of 2021. During his tenure, Dr. Devaiah led the Institute's cross-disciplinary work which included bringing new technology and expanded use cases from the bench to the bedside, intersecting with the wraparound systems integral to health care. The domain's programs and research lines included device and drug innovations for diagnostics and therapeutic applications, digital health platforms, educational innovations, public health policy, and Social Determinants of Health and their impact. He continues to serve in similar capacities, through continuing work in the innovation space within and outside the University, and in service to different Societies and organizations.

Lindsay DeVries, PhD is an audiology reviewer on the ENT Team at the Food and Drug Administration. She completed her Doctorate in Audiology (Au.D.) in 2011 at the University of Washington in Seattle, Washington. After graduating, she worked as an audiologist for two years at ENT Associates SW in Olympia, WA. In 2013, she returned to the University of Washington for her Ph.D. in Speech and Hearing Sciences with a focus on cochlear implant psychophysics, completing in 2018. She joined the University in Maryland in 2018 for a post-doctoral position studying aging, cognition, and hearing loss. She joined the FDA in 2020.

Malvina B. Eydelman, MD (Workshop Committee Member) for 25 years, as an Expert Medical Officer, Senior Medical Advisor and Director of FDA's Office of Ophthalmic, Anesthesia, Respiratory, ENT, & Dental 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. Dr. Eydelman has organized multi-stakeholder public- private 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.). Dr. Eydelman has been granted a U.S. patent, published nearly 100 peer-reviewed articles, book chapters, and monographs and presented over 200 lectures worldwide.

Jason Galster, PhD, MS is Director of Clinical Research at Advanced Bionics, overseeing the clinical investigation of emerging technology, regulatory clinical affairs, and scientific collaborations that focus on the treatment of hearing loss with cochlear implants and hearing aids. He is an internationally recognized author, lecturer, and adjunct professor in audiology.

Bruce J Gantz, MD is currently Professor and Chair emeritus of the Department of Otolaryngology—Head and Neck Surgery and Professor of Neurosurgery at the University of Iowa Carver College of Medicine. He received his Bachelor of Science and Masters degree in Otolaryngology from the University of Iowa, where he completed medical school. A surgical internship was served at the University of Utah College of Medicine. He returned to the University of Iowa for his Otolaryngology residency. Upon completing a Neurotology Clinical Fellowship with Dr Ugo Fisch at the Universitätsspital Zürich, Otorhinolaryngologische Klinik und Poliklinik, in Zürich, Switzerland, he joined the faculty at the University of Iowa Department of Otolaryngology—Head and Neck Surgery. Dr. Gantz's research interests include cochlear implants, management of facial paralysis, hearing preservation in acoustic tumor and skull-base surgery, and management of cholesteatoma. He is the principle investigator of the Iowa Cochlear Implant Clinical Research Center, funded by the NIH since 1985. In December 2017 the Center was awarded their seventh five-year NIH renewal that will run through 2022. He has led the Iowa CI Team in the development of the Hybrid Cochlear Implant, for which he holds a patent. He is a member of many otolaryngology professional societies and has Board Certification from the American Board of Otolaryngology, as well as subspecialty certification in Neurotology from the ABOto. Some of his honors include being named the Brian F McCabe Distinguished Chair in Otolaryngology—Head and Neck Surgery by The University of Iowa Carver College of Medicine; The University of Iowa Carver College of Medicine Distinguished Alumnus Award for Achievement in 2005; University of Iowa Carver College of Medicine Distinguished Mentor Award 2010; elected to the National Academy of Medicine in 2000; President of the Association of Research in Otolaryngology; President of the American Neurotology Society; President of the American Otological Society; and President of the American Board of Otolaryngology. In 2016, he was awarded the Shambaugh Prize for lifetime achievement from the Collegium Oto-Rhino-Laryngologicum Amicitiae Sacrum. His publications include 252 peer-reviewed papers and he has contributed to over 58 books and chapters.

Richard Gliklich, MD is the CEO of OM1, Inc. Previously, he was founder and CEO of Outcome, which he led from inception through its acquisition by Quintiles. Dr. Gliklich is well known in the areas of registries, outcomes, and analytics. He is senior editor of the landmark publication by the U.S. Agency for Healthcare Research and Quality (AHRQ) handbook "Registries for Evaluating Patient Outcomes: A User's Guide" and the PI for the Outcomes Measures Framework, which focuses on standardization of outcomes measurement. He has led several key national and international efforts focused on evaluating the safety, effectiveness, value and quality of healthcare. Dr. Gliklich also holds several patents for both health outcomes systems and medical devices. Dr. Gliklich is a graduate of Yale University and Harvard Medical School and a former Charles A. Dana Scholar at the University of Pennsylvania. He is also an otolaryngologist and the Leffenfeld Professor, part-time, at Harvard Medical School.

Jedidiah (Jed) Grisel, MD is an otolaryngologist at Texoma ENT & Allergy in Wichita Falls, TX. Texoma ENT & Allergy is a founding member of ENT Specialty Partners, a Texas-based Management Service Organization (MSO) for otolaryngologists. Dr. Grisel is also a co-founder of the Auditory Implant Initiative – a grassroots, collaborative group of hearing professionals dedicated to improved cochlear implant outcomes through data sharing. This nonprofit group created the HERMES database, a collection of cochlear implant outcomes representing dozens of hearing centers and over 9000 implant recipients.

Rene Gifford, PhD is a Professor in the Department of Hearing and Speech Sciences at Vanderbilt University Medical Center and is the Director and PI of the Cochlear Implant Research Laboratory. Her current research interests include speech and auditory perception via combined electric and acoustic stimulation (EAS), patient-specific variables impacting postoperative outcomes, and spatial hearing abilities of individuals combining hearing aids and cochlear implants. Dr. Gifford's research has been NIH funded for 20 years, she has published over 130 peer-reviewed articles, multiple book chapters, and she authored a book, now in its second edition, entitled "Cochlear Implant Patient Assessment: Evaluation of Candidacy, Performance, and Outcomes."

John H.L. Hansen, PhD (IEEE S'81-M'82-SM'93-F'07) received his Ph.D. and M.S. degrees in Electrical Engineering from Georgia Institute of Technology, and B.S.E.E. degree from Rutgers University, College of Engineering. He was awarded the honorary degree "Doctor Technices Honoris Causa" from Aalborg University (Aalborg, DK) (April 2016) for his contributions to speech signal processing and speech/language/hearing science. He currently serves as Assoc. Dean for Research for the Erik Jonsson School of Engineering & Computer Science, Professor of Electrical Engineering, and holds a joint appointment as Professor in the School of Behavioral and Brain Sciences (Speech & Hearing) and Univ. of Texas at Dallas. He previously served as Dept. Chair of Speech, Language and Hearing Sciences (SLHS), Univ. of Colorado – Boulder. He is an IEEE Fellow (2007), ISCA Fellow (2010), and received Acoustical Society of America's 25 Year Award (2010). He has held leadership positions in the field including ISCA President (2018-2021), Vice-Chair on U.S. Office of Scientific Advisory Committees (OSAC), Chair of IEEE Speech-Language Processing Technical Committee (SLTC); Technical Advisor to the U.S. Delegate for NATO (IST/TG-01), Assoc. Editor for many journals. He oversees the Center for Robust Speech Systems (CRSS) – Cochlear Implant Processing Lab (CILab) at UTDallas. His research interests span the areas of analysis/modeling of speech/speaker traits, acoustics - hearing and cochlear implant advancements, and speech enhancement and machine learning. He has supervised 95 PhD/MS thesis candidates and is author/co-author of +800 journal and conference papers including 13 textbooks in the field of speech processing, language, and hearing technology.

Marlan Hansen, MD is a professor of Otolaryngology-Head and Neck Surgery, Neurosurgery, and Molecular Physiology and Biophysics and the Co-Director of the Institute of Clinical and Translational Science at the University of Iowa He is a clinician-scientist trained in neurotology/skull base surgery and cell and molecular neurobiology. His research involves multidisciplinary approaches to basic, translational, and clinical investigations broadly related to auditory neurobiology. His team explores the response of the auditory nerve to injury, its regenerative capacity, and methods to improve cochlear implant outcomes using in vitro systems, animal models, and human subjects. His work is funded by the NIH, NSF, Department of Defense, and industry sponsors.

Meredith Holcomb, AuD, CCC-A is an Associate Professor and the Director of the Hearing Implant Program at the University of Miami Ear Institute. She is the immediate past-Chair of the American Cochlear Implant Alliance Board of Directors, and she currently serves as the ASHA appointed representative on the Joint Committee for Infant Hearing. Dr. Holcomb is a consultant for Advanced Bionics, Med El, Cochlear, Hemideina, and the Institute for Cochlear Implant Training Advanced Audiology Course. Dr. Holcomb demonstrates a strong commitment to education, mentorship, and clinical research primarily focused on cochlear implant outcomes in children and adults.

Nilsa Loyo-Berríos, PhD, MSc, (Workshop Committee Co-chair) is Acting Associate Director for the Office of Health Technologies 1 (OHT1) in the Center for Devices and Radiological Health (CDRH). She joined the FDA in 2005 as a regulatory epidemiology reviewer for medical devices. She has extensive experience on the application of epidemiological principles, particularly on observational methodologies and analyses, and on the evaluation and surveillance of medical devices throughout the total product life cycle (TPLC). Dr. Loyo-Berrios has extensive experience providing oversight for epidemiological regulatory reviews, infrastructure development and partnerships, and policy for mandated postmarket studies (Post-Approval Studies and Section 522 Studies). As *Acting Associate Director* in OHT1 she leads initiatives to develop, strengthen or leverage real-world data sources, and regulatory research for TPLC device evaluation. She served as a member of the Methods Sub-committee of the National Evaluation System of health Technologies (NEST). Dr. Loyo-Berríos has authored and co-authored publications in prestigious peer reviewed journals such as JAMA, Journal of Bone Joint Surgery, Circulation Cardiovascular Quality Outcomes, Journal of Women's Heath, Journal of Human Lactation, and the American Journal of Epidemiology, among others.

Eric A. Mann, MD, PhD currently serves as a medical officer in the Office of Health Technology 1 in the Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration. He received his undergraduate degree (B.A.) in Premedical Science from Lehigh University. He earned his medical degree and his Ph.D. in Microbiology and Immunology from the Medical College of Pennsylvania in 1988. He completed a residency in Otolaryngology-Head and Neck Surgery at the University of Connecticut Health Center, Farmington, CT and is board-certified in his specialty. He previously served as attending surgeon at the Walter Reed Army Medical Center in Washington, D.C. and as a senior staff surgeon at the NIH Clinical Center in Bethesda, MD. He has been actively involved in the premarket regulation of medical devices since his arrival at CDRH in 2001.

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE (Workshop Committee Member) serves as the Associate Director of the Office of Clinical Evidence and Analysis, at the FDA, Center for Devices and Radiological Health (CDRH). Prior to this position she was the Director of the CDRH Division of Epidemiology. Under her leadership, in 2010 FDA/CDRH launched its MDEpiNet Initiative. Dr. Marinac-Dabic also led the development of the International Consortium of Orthopedic Registries Initiative; International Consortium of Cardiac Registries and International Consortium of Vascular Registries. From 2015-2018 she led the Registry Working Group at the International Medical Device Regulators Forum to develop series of essential principles for international convergence of registry-generated data for regulatory decision making. Since 2017, she leads the PCORTF- funded effort to establish Women's Health Coordinated Registry Network for addressing clinical questions on devices, therapies, and their combinations for the treatment of uterine fibroids, pelvic floor disorders and female sterilization. She is a Fellow of the International Society of Pharmaco-epidemiology and Therapeutic Risk Management, Member of the Executive Operations Committee of the MDEpiNet, Member of the Steering Committee of Transcatheter Valve Therapies Registry, National Breast Implants Registry and Oxford-based IDEAL Collaborative, EXCITE International Collaborative and International Consortium of Breast Registry Activities. Prior to coming to FDA, she garnered experience in obstetrics, gynecology, and epidemiology in the academic and hospital settings as well as teaching experience in academic environment.

Theodore R. McRackan, MD, MSCR, is the medical director of the Cochlear Implant Program and director of the Skull Base Center in the Department of Otolaryngology – Head and Neck Surgery at the Medical University of South Carolina (MUSC). Dr. McRackan received his medical degree from MUSC, completed his residency at Vanderbilt University and completed his fellowship in otology-neurotology and skull base surgery at the House Ear Clinic. He subsequently received his Master of Science in Clinical Research at MUSC. Dr. McRackan's clinical practice is focused on comprehensive management of ear, hearing, balance, and skull base disorders in adults and children. His research focuses on developing a better understanding of the communication, health, social, and economic benefits of cochlear implantation in adults through the expansion of outcomes beyond traditional measures. Moreover, his interests include implementing such measures and other interventions to provide a patient-centered, precision medicine approach to improve cochlear implant functional outcomes and clinical care. His research has been supported by the National Institutes of Health (National Institute on Deafness and Other Communication Disorders and National Center for Advancing Translational Sciences), the American Cochlear Implant Alliance, and the Doris Duke Foundation.

Barbara Mellert, MPH is the parent of two adult sons with bilateral cochlear implants. She has long been involved with parent support and advocacy regarding cochlear implants and hearing loss. Barbara serves on the board of the American Cochlear Implant Alliance as their parent representative. She currently is the administrator of the Facebook group Parents of Children with Cochlear Implants, which is a large group that provides information and support to 14,000+ members. Barbara and her husband, Hugh, served on the state of New Hampshire's newborn hearing screening taskforce. She also managed the Listen-up listserv, which also was a source of support and information for parents with children with hearing loss. Locally, Barbara served on the board of the Special Needs Support Center. She is a current New Hampshire Public Radio Community Advisory Board member. She works at Dartmouth College where she serves as a client technology consultant in the Information, Technology and Consulting division.

Nandu Nandkumar, PhD (Workshop Committee Member) received his PhD degree from Duke University in Electrical Engineering. He worked for ten years in the private sector in telecommunications, digital speech processing and software. He is an author of several papers on Speech and Audio processing in the areas of voice compression and noise reduction in speech. He started as an engineering reviewer at the FDA in the Ear, Nose and Throat Branch and was its Branch Chief for almost 10 years, contributing to advancements in regulatory science in the device areas of ENT and Sleep medicine. He currently serves as the Director of the Division of Dental and ENT devices.

Vasum Peiris, MD, MPH as Chief Medical Officer and Director for Pediatrics and Special Populations at the FDA CDRH, Vasum provides vision and executive, clinical, and scientific leadership. He serves as the Center's senior expert on pediatric clinical science and practice, leading development and implementation of novel strategies, programs and initiatives optimizing innovation, development, assessment, regulation, and safe use of medical devices intended for pediatric and special populations. His dynamic leadership engenders relationships and synergy within and among matrixed public and private sector organizations that enhance the ability of the Agency to optimally fulfil its public health mission. Vasum's collaborative, innovative, and cross-cutting work at the FDA has been recognized with over eight awards including the Commissioner's Special Citation and the Commissioner's Award of Excellence. Prior to joining the FDA, Vasum was the Joon Park, M.D. Endowed Chair for Medical Excellence and Chief of Pediatric and Adult Congenital Cardiology at Texas Tech University Health Sciences Center, with appointments in both the Department of Pediatrics an Internal Medicine, and the Graduate School of Biomedical Sciences. In addition to leading, expanding and integrating a complex multi-subspecialty clinical service across the health system enterprise, caring for patients from the pre-natal period through 50-plus, and teaching medical, nursing, pharmacy, graduate, and law students, Vasum served in multiple senior leadership roles for the University and Medical Center, including development of the Clinical Research Institute and as inaugural faculty creating the Department of Public Health. Vasum

currently provides clinical care at Children's National Hospital, with appointment as adjunct Professor at The George Washington School of Medicine and Health Sciences. Vasum is triple Board-certified in Pediatrics, Pediatric Cardiology and Adult Congenital Cardiology by the American Board of Pediatrics and the American Board of Internal Medicine. He has been elected to Fellow of the American Academy Pediatrics, the American Society of Echocardiography, and the American College of Cardiology. He has been invited faculty for national and international scientific and professional conferences, an invited visiting professor and lecturer at leading universities, and an ad-hoc reviewer for premier scientific journals. He is an accomplished author and nationally recognized research scientist. Vasum earned his undergraduate degree at Yale University and his graduate degree at the Yale School of Medicine, Department of Epidemiology and Public Health. He completed medical school at The University of Vermont College of Medicine, residency at Yale School of Medicine/Yale-New Haven Hospital, and fellowship and senior fellowship at Harvard Medical School/Boston Children's Hospital/Beth-Israel Deaconess Medical Center.

Shu-Chen Peng (Workshop Committee Member) is the Assistant Director for the Ear, Nose, Throat (ENT) Devices Team, at Center for Devices and Radiological Health, Food and Drug Administration. She completed her Ph.D. in Speech and Hearing Sciences, as well as her master's degree in clinical audiology at the University of Iowa, where she accumulated clinical and research experience in the field of cochlear implants, focusing on outcomes in both children and adult patients. She joined the ENT devices team in 2006 and worked for 10 years as an audiology reviewer. She then transitioned to be the Team Lead and then later became the Assistant Director for the team. Dr. Peng is involved in various aspects of regulatory approvals for cochlear implants and other ENT devices.

Eric Pepin Lehalleur serves as Chief Product Innovation Officer for Cochlear Implants at Oticon Medical. In his current position, he is responsible for maintaining organizational Product Innovation strategy, defining the requirements for new technology implementations, and releasing them to market. Since he joint Oticon Medical he leads multi disciplinarity Research and Development teams responsible for bringing to market Cochlear Implant solutions. Under his leadership, Oticon Medical has obtained Premarket Approval for the Neuro Cochlear Implant System (NCIS) in June 2021. Prior joining Oticon Medical in 2015, he held for 14 years various Program Management and Research and Development Management positions in the semiconductor industry leading connectivity and automotive chipsets development. From 1991 to 2001, he garnered experience in the Satellite industry. He holds a Master's Degree of Engineering in Industrial Automation.

Nicholas S. Reed, AuD is an Assistant Professor in the Department of Epidemiology at Johns Hopkins Bloomberg School of Public Health with a joint appointment in the Department of Otolaryngology-Head and Neck Surgery (Audiology) at Johns Hopkins School of Medicine. His research focuses on direct-to-consumer hearing care, characterizing hearing aid use in the United States, the relationship between hearing loss and health care outcomes/interactions (e.g., satisfaction with care, inpatient safety, quality of care, delirium, etc.), and whether interventions targeting hearing loss can mitigate these associations. Dr. Reed is core faculty at the Cochlear Center for Hearing and Public Health where he is the Director of the Audiology core. In this capacity, he oversees the integration of hearing measures and hearing care into numerous cohort studies and clinical trials (Baltimore Longitudinal Study of Aging, the Atherosclerosis Risk in Communities Neurocognitive Study, the BIOCARD Study, the Baltimore Epidemiologic Catchment Area Study, National Health Aging and Trends Study, and Aging and Cognitive Health Evaluation in Elders).

Anindita (Annie) Saha is the Assistant Director for the Digital Health Center of Excellence (DHCoE) at the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Ms. Saha is leading the development of partnerships, regulatory science, strategic planning, and operations for the newly formed DHCoE to empower digital health stakeholders in advancing healthcare. Additionally, Annie helped incubate and continues to support CDRH's patient science and engagement efforts to advance the science and adoption of patient input as evidence, including patient preference information (PPI), clinical outcome assessments (COAs) including patient-reported outcomes (PROs), and patient-generated health data (PGHD). These efforts include researching the use of digital health technologies to capture the patient perspective. Previously, Annie was the Director of Partnerships to Advance Innovation and Regulatory Science (PAIRS) where she oversaw a broad program portfolio, supporting a number of strategic partnership and regulatory science programs for CDRH. This included relationships with the Medical Device Innovation Consortium and other public-private partnerships, Network of Experts, Critical Path, and technology transfer. Ms. Saha began her FDA career as a researcher in the CDRH's Office of Science and Engineering Laboratories in the Division of Imaging and Applied Mathematics in imaging display technologies before working to coordinate Critical Path and Regulatory Science activities for the Center. Ms. Saha has a Bachelor of Science in Bioengineering and Minor in History from the University of Pittsburgh. She was a student researcher at the McGowan Institute for Regenerative Medicine working in tissue engineering and wound healing.

Veronica Sansing-Foster, PhD, MS (Workshop Committee Co-chair) is a Senior Epidemiologist for FDA's Center for Devices and Radiologic Health, Office of Clinical Evidence and Analysis. She co-leads the development of Cochlear Implants Innovation, Research and Advancement (CIRCA) which includes the Minimum Core Data Elements (MCDE) for cochlear implants and the CIRCA Workshop. She earned an Honor's BA in psychology from the University of Chicago in 1999 and earned her MS and PhD in Psychiatric Epidemiology from the University of Pittsburgh Graduate School of Public Health in 2008 and 2010, respectively. Dr. Sansing-Foster began her career at FDA in 2010 where she worked as an Acting Branch Chief and Lead Epidemiologist CDRH, leading a team of epidemiologists in the design and interpretation of numerous postmarket studies for cardiovascular, neurological, and physical medicine devices. She conducted numerous epidemiologic studies for medical devices and helped design medical device registries. Dr. Sansing-Foster progressed over to FDA's Center for Drug Evaluation and Research (CDER) in 2014 where she conducted epidemiologic research for medications. She has numerous awards for her research including the 2012 Journal of Nuclear Cardiology Best Paper Award and the FDA's 2017 Dr. Frances O. Kelsey Drug Safety Excellence Award.

Flora Sandra Siami, MPH (Workshop Committee Member) brings 25 years of experience in corporate management, clinical and RWE research, and strategy and business development to her role as senior vice president of NESTcc. Ms. Siami guides the strategy and operations for NESTcc programs to advance the goals of stakeholders including patients, providers, payers, industry, regulators, and others. She also leads NESTcc's efforts to become a trusted platform in the timely generation of real-world evidence (RWE) and a key partner in solving pre- and post-market challenges in the medical technology space. Prior to joining NESTcc, Ms. Siami served as staff vice president of Clinical Research, Regulatory Affairs, and Quality Assurance at HealthCore, Inc. In this role, Ms. Siami led the Clinical Research business unit that directed early- and late-phase trials utilizing the real-world data ecosystem, with a specific interest in rare, orphan, and underserved diseases, as well as pediatric, elderly, and minority populations. She also oversaw the business unit's pharmacovigilance and medical device activities, quality system administration, and domestic and international regulatory affairs efforts in 31 countries. She served in leadership positions for 15 years at New England Research Institutes, Inc., including as the scientific integrity officer, and oversaw the NERI Institutional Review Board. In addition, Ms. Siami has a proven history in leading multi-stakeholder collaborations for clinical and regulatory decision-making in the medical device industry. She has given over 45 scientific presentations and has over 50 publications in major medical journals and book chapters. Ms. Siami received her BS from Vanderbilt University and MPH from George Washington University.

Art Sedrakyan, MD, PhD (Workshop Committee Member) is a tenured professor at Weill Cornell Medicine and directs the Institute for Health Technologies and Interventions. The institute is the academic home of the Medical Device Epidemiology Network's (MDEpiNet) Coordinating, Science, and Infrastructure Center. Dr. Sedrakyan directs the Center and is the initiator (with FDA) of major national and international coordinated registry networks (CRN) that form the backbone of MDEpiNet along with many public-private partnerships. He is a trained CT surgeon and a graduate of Johns Hopkins University with PhD in Health Policy and Management. He was a senior adviser at FDA and had appointments as senior service officer/senior adviser at the Agency for Healthcare Research and Quality. Prior to appointments at DHHS he worked in the United Kingdom as a faculty at Royal College of Surgeons (RCS) of England and London School of Hygiene. He is currently serving as a ranking member and was previously the Vice-Chair of Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). He is the Vice-Chair of the IDEAL initiative with leadership area in devices. Since January 2017 he is serving as a specialist advisor for Australian Therapeutic Good Administration (TGA) and Honorary Professor at UNSW Big Data Centre where he helped establish Australian MDEpiNet Center. Since May 2019 he is serving as a Co-Editor-In-Chief the 'BMJ Surgery, Interventions &Health Technologies' (BMJ-SIT).

Lawrence Simon, BCBS is the Medical Director for Utilization Management and Coding and Reimbursement for Blue Cross and Blue Shield of Louisiana (BCBSLA), where he also serves as the Chair of the Credentialing and Medical Quality Management Committees. In these roles, Dr. Simon helps with numerous Community Outreach, Payment Integrity, and Cost Containment initiatives. He is also a member of the AMA CPT Editorial Panel, serving on the Executive Committee of the Panel and as Co-Chair of the Molecular Pathology Advisory Group and the PLA Technical Advisory Group. He also advises the Blue Cross and Blue Shield Association on Otolaryngology medical policies and coding education in general. A diplomate of the American Board of Otolaryngology and a Fellow of the American College of Surgeons, Dr. Simon has over 13 years of experience in Health Policy and Healthcare Reform, and he has presented over 170 lectures and seminars on these topics. A Rotarian and animal rescuer, Dr. Simon enjoys spending his time outside of work serving his community, helping the shelters and abandoned dogs of Louisiana, and celebrating life with family and friends.

Vahan Simonyan, MS, PhD has a scientific background in Chemistry, Physics and Mathematics, Nanotechnology and Quantum Statistical Thermodynamics, Biotechnology and Biomedical Informatics. He currently serves as a Senior director of Bioinformatics at the CRISPR Therapeutics, Chief Scientist at the WHISE consortium and as a Professor of biostatistics and Bioinformatics at the George Washington University. Vahan is a prolific author of publications in physics, chemistry, quantum chemistry, nanotechnology, biotechnology, population dynamics, and bioinformatics. His accomplishments in academic and R&D technology carriers have been complemented with the success of technology leadership and executive roles at NIH and FDA where he established large-scale and complex, science-heavy R&D infrastructures.

Donna L. Sorkin, MA (Workshop Committee Member) is Executive Director of the American Cochlear Implant Alliance, a national organization devoted to expanding access to cochlear implantation for all who may benefit. She previously served as Executive Director of the Hearing Loss Association of America and the Alexander Graham Bell Association for the Deaf and Hard of Hearing. She was also previously Vice President of Consumer Affairs at Cochlear Americas where she led public policy initiatives and other activities aimed at the broad life needs of cochlear implant users. She has served on federal, corporate and university boards including the U.S. Access Board as a Presidential appointee and the NIDCD/NIH Advisory Board. She holds a Masters in Public Policy from the Kennedy School of Government at Harvard University.

Martha (Marti) Velezis, MPH, MS (Workshop Committee Member) is an independent consultant with over twenty years of experience in standards development and implementation, project management, enterprise architecture and business analysis. She serves as a Unique Device Identification (UDI) technical expert and works with manufacturers and international regulatory agencies and authorities to improve the adoption of UDI across the device product lifecycle. Her current work focuses technical support for UDI requirements development and analysis, data modeling, data standards development in Health Level Seven (HL7), as well as support for the MDEpiNet Coordinated Registry Networks (CRNs) for the Food and Drug Administration's Center for Devices and Radiological Health (CDRH).

Nancy Young, MD is the Lillian S. Wells Professor of Pediatric Otolaryngology at the Northwestern University Feinberg School of Medicine. She is Head of the Section of Otology and Neurotology within the division of Otolaryngology, and Medical Director of Audiology & the Cochlear Implant Programs at Ann and Robert H Lurie Children's of Chicago. She is also a member of Northwestern's Institute for Innovations in Developmental Sciences and Fellow of the Knowles Hearing Center. She is a member of the Council (leadership) of the American Otological Society and was a founding board member of the American Cochlear Implant Alliance. Dr. Young is recipient of an NIH/NIDCD R21 grant (with Multi-PI Patrick C W Wong, PhD) to investigate prediction of language after cochlear implantation based on brain structure and function. The long-term goal of this research is to develop custom therapies to maximize language and cognition.

Ting Zhang, PhD completed her Medical Degree at Beijing Medical University, China, and her residency training as an ENT physician at the 3rd hospital of Beijing Medical University. She then completed her Ph. D. degree in Audiology at University of Maryland, College Park, where she studied speech perception, psychophysics, and cochlear implant focusing on combined electric and acoustic stimulation. Dr. Zhang then completed a NIH F32 art fellowship in cochlear implant at Arizona State University. Dr. Zhang began her career at FDA when she joined the ENT team at FDA as an audiology reviewer in 2014.

Terry Zwolan, PhD is Director of Audiology at Hearing First – an educational endeavor of the Oberkotter Foundation. She is Professor Emerita in the Department of Otolaryngology – Head and Neck Surgery at Michigan Medicine where she served as Director of the Cochlear Implant from 1990-2021. Dr. Zwolan is a co-founder of the American Cochlear Implant Alliance and served on its initial Board of Directors. She serves as Director for two courses for the Institute for Cochlear Implant Training (ICIT) and serves as an adjunct faculty member for Wayne State University's AUD Program. She has authored/co-authored numerous articles and chapters related to adult and pediatric cochlear implants.

Thank you

THANK YOU!

A special thank you is extended to all the Planning Committee members, assistants, and administrators who worked collaboratively to organize and conduct this meeting.

Workshop Planning Organizations:

American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS)
American Cochlear Implant Alliance (ACIA)
Boston Medical Center
US Food and Drug Administration, Center for Devices and Radiological Health
Medical Device Epidemiology Network (MDEpiNet) Coordinating Center at Weill Cornell Medicine
National Evaluation System for health Technologies (NESTcc) Coordinating Center
National Institute on Deafness and Other Communication Disorders