Cochlear Implant Innovation, Research and Advancement (CIRCA) Workshop

February 1-2, 2022

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

About the Workshop:

The Food and Drug Administration (FDA) and the Medical Device Epidemiology Network (MDEpiNet) are cosponsoring a **C**ochlear **I**mplants Innovation, **R**esear**c**h and **A**dvancement (CIRCA) Virtual Workshop, to be held February 1-2, 2022. As cochlear implant technologies advance, new applications arise such as cochlear implants with capabilities for remote and artificial intelligence/machine learning-assisted programming, expansion of patients' candidacy using real-world evidence (RWE), preservation of residual hearing, new speech coding strategies, and the need for consensus on core data elements necessary for the clinical evaluation and research of cochlear implants.

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.

DAY 1
February 1

CIRCA WORKSHOP CONFIRMED SPEAKERS

TIME		TOPIC	CONFIRMED SPEAKER
8:30 AM	8:45 AM	**Day 1: Welcome and Introductory Remarks**	Dr. Malvina Eydelman, *Director of the Office of Health Technology, FDA* Dr. Vasum Peiris, *Chief Medical Officer and Director of Pediatrics and Special Populations, FDA*
8:45 AM	10:55 AM	**Session I: Cochlear Implants Technology and Regulation**	
		Cochlear Implants Regulatory History and Challenges, FDA Perspective	Dr. Nandu Nandkumar, *Director, Division of Dental and ENT Devices, FDA*
		Cochlear Implants Technological Developments, Industry Perspective	Elizabeth Gfoeller, *Medel*
		Hearing Loss and Cochlear Implants Patients' Perspective: Adults & Pediatrics	Donna Sorkin, *Executive Director, American Cochlear Implant Alliance* Barbara Mellert, *Patient Advocate*
		Clinical Perspectives on Cochlear Implants, Academia/Clinical Perspective	Marlan Hansen, *Otolaryngologist, University of Iowa Hospitals and Clinics*
		Payer's Perspective: CMS & Private	
		Moderated Q&A for Session I	co-moderators: Dr. Eric Mann, *Chief Medical Officer, Office of Ophthalmic, Anesthesia, Respiratory, ENT & Dental Devices, FDA* Dr. Nicholas Reed, *Faculty in the Departments of Epidemiology and Otolaryngology (Audiology) at Johns Hopkins University*
10:45 AM	10:55 AM	*Break*	
10:55 AM	1:10 PM	**Session IIa: Evaluation of Cochlear Implants Throughout the Total Product Life Cycle**	
		Evidence Needs for Patients Candidacy Criteria	Dr. Terry Zwolan, *Director of Audiology, Hearing First* Dr. Meredith Holcomb, *Director of Hearing Implants, University of Miami (FL)*
		Considerations for Preservation of Residual Hearing and Electroacoustic Stimulation	Dr. Craig Buchman, *Lindburg Professor and Head Otolaryngology—Head & Neck Surgery, Washington School of Medicine, St. Louis*
		Evidence Needs and Considerations for Individual Ear Indications	Dr. Oliver Adunka *Professor & Director of Otology, Neurotology and Cranial Base Surgery, Ohio State University*

TIME		TOPIC	CONFIRMED SPEAKER
		Evidence Needs and Considerations for Pediatric Patients	Dr. Nancy Young, *Medical Director, Audiology & Cochlear Implant Programs, Lurie Children's Hospital*
		Needs and Consideration Postmarket Surveillance	Dr. Shu-Chen Peng, *Audiology & Senior Lead Reviewer, FDA*
		Disparities in Access to Cochlear Implants	Dr. Anand Devaiah, *Professor and Otolaryngologist, Boston Medical Center* Dr. Matthew Bush, *Professor & Endowed Chair in Rural Health Policy, University of KY College of Medicine*
		Moderated Q&A for Session IIa	René Gifford, *Vanderbilt University*
1:10 PM	1:55 PM	*Lunch Break*	
1:55 PM	3:55 PM	**Session IIb: Evidence Needs to Support Cochlear Implants Innovation**	
		Emerging Cochlear Implant Technologies and Associated Evidence Needs	
		Alignment of the Regulatory and Reimbursement Systems: Impact on the Cochlear Implants Community	
		Real-World Evidence for Regulatory Purposes: Needs and Opportunities	Dr. Veronica Sansing-Foster, *Senior Epidemiologist, FDA* Dr. Nilsa Loyo-Berríos, *Associate Director, FDA*
		Digital Health Opportunities for Innovation	
		Capabilities Patient Reported Outcome Measures	Dr. Theodore McRackan, *Medical Director, Cochlear Implant Program, Medical University of South Carolina*
		Moderated Q&A for Session IIb	Dr. Nandu Nandkumar, *Director, Division of Dental and ENT Devices, FDA* Dr. Anand Devaiah, *Professor and Otolaryngologist, Boston Medical Center*
3:55 PM	4:05 PM	**Day 1 Concluding Remarks**	Dr. Art Sedrakyan, *Professor, Weill Cornell Medicine, Medical Device Epidemiology Network (MDEpiNet)*

DAY 2
February 2

TIME		TOPIC	CONFIRMED SPEAKER
8:30 AM	8:45 AM	**DAY 2: Welcome**	
8:45 AM	10:45 AM	**Session IV: Working on Data Infrastructure**	
		NESTcc Overview	Sandra Siami, *Senior Vice President, National Evaluation System for health Technology* (NESTcc)
		Coordinated Registries Networks (CRN) as Foundation for Device Evaluation	Dr. Art Sedrakyan, *Professor, Weill Cornell Medicine, Medical Device Epidemiology Network (MDEpiNet)*
		Overview of Cochlear Implant Registries	Richard Glikilch, *MD (OM1)*
		The Delphi Process: Stakeholders Effort to Identify Minimum Core Data Elements (MCDE) for Cochlear Implants	Suvekshya Aryal, *Senior Research Analyst, Weill Cornell Medicine, MDEpiNet*
		International Registries for Cochlear Implants	
		Moderated Q&A for Session IV	Co-moderators: Dr. Shu-Chen Peng, Audiology & Senior Lead Reviewer, FDA Dr. James C. Denneny, *Executive Vice President/CEO, American Academy of Otolaryngology - Head and Neck Surgery (AAO – HNS)*
10:45 AM	10:55 AM	Break	
		Session V: Tailoring Methods to Data Infrastructure	
		Implementation of MCDE – Lessons Learned	
		Implementation of MCDE – Future Adoption and Opportunities: Industry, Clinical, Regulatory	Martha Velezis, *Data Standards and Interoperability Consultant (FDA), Chair/CRN Architecture Task Force (MDEpiNet)*
		Future Application for Hearing Aids	Dr. Eric Mann, *Chief Medical Officer, FDA*
		Moderated Q&A for Session V	Dr. Danica Marinac-Dabic, *Associate Director, FDA* Dr. Art Sedrakyan, *Professor, Weill Cornell Medicine, Medical Device Epidemiology Network (MDEpiNet)*
12:25 PM	12:40 PM	**Concluding Remarks and Next Steps**	Dr. Danica Marinac-Dabic, *Associate Director, FDA*