



2024 Diagnostics and Tracking Research Roundtable for Epilepsy

Wednesday, April 24, 2024
Pendry – The Wharf
Washington, DC

AGENDA

Wednesday, April 24, 2024

2024 Diagnostics & Tracking Research Roundtable for Epilepsy

Meeting Objectives:

- Optimize pathways to approval and reimbursement
- Develop consensus towards seizure annotation requirements

7:00 – 8:00	Registration and Breakfast	
--------------------	-----------------------------------	--

8:00 – 8:15	Meeting Welcome & Updates	
8:00 – 8:10	Welcome, Meeting Goals and Deliverables, 2024 Challenge and overview	Drs. Caitlin Grzeskowiak, Jacqueline French and Nathan Fountain
8:10 – 8:15	Welcoming Remarks	Bernice Lee

8:15 – 8:40	Lived Experience	
8:15 – 8:25	Overview from Danny Did Foundation	Mary Duffy & Tom Stanton
8:25 – 8:35	Family Perspectives	Jennifer Sime & Lauren Knepper
8:35 – 8:40	Q&A	Moderator: Tom Stanton

8:40 – 9:25	Session I: FDA input	
8:40-8:55	Efficient pathways from FDA approval to reimbursement	Dr. David McMullen
8:55 – 9:05	Total Product Lifecycle Advisory Program	Dr. April Marrone
9:05-9:20	Handling Artificial intelligence and Machine Learning algorithms in an FDA application	Dr. Jay Gupta
9:20-9:45	Discussion	

9:45-10:00	Session II - Mapping the Path	
9:45-10:00	Mapping the landscape: developing pathways to coverage/reimbursement	Dr. Nathan Fountain & Michael Gaba
10:00-11:00	Session III: CPT Codes	
10:00 - 10:20	New CPT Codes	Dr. Marc Nuwer
10:20 – 10:30	Discussion	
10:30-10:50	New ICD-PCS code creation for hospital reimbursement for inpatient procedure (NTAP)	Dr. Raymond Woo
10:50 – 11:00	Discussion	
11:00-11:15	Networking Break	
11:15-12:15	Session III CPT Codes Continued	
11:15-11:35	Using existing codes Remote monitoring & physiological monitoring	Dr. Nathan Fountain
11:35 – 11:50	Identifying relevant CPT codes Demonstrating relevancy of technology to code	Judith Lenane
11:50 – 12:15	Discussion	
12:15 – 1:15	Lunch	
1:15-3:15	Session IV: Reimbursement	
1:15 – 1:30	Epilepsy Foundation Advocacy for coverage of seizure detection devices	Laura Weidner
1:30 – 1:40	Lesson learned on a pathway to reimbursement	Dr. John Hixson
1:40 – 1:50	Impact of FDA Clearance on Reimbursement	Parth Amin
1:50 – 2:10	CMS Resources for Medical Technology Innovators	TJ Sutphin
2:10 – 2:30	Overview of the NTAP Program	CMS
2:30 – 2:40	Intersection of CMS and FDA	Michael Gaba

2:40 – 3:15 Discussion; How to Overcome Reimbursement Challenges

3:15-3:30 Break

3:30-5:15 Session V: Ground Truths for EEG Annotation

3:30-3:50	FDA: Principals of clinical review for seizure activity	Dr. Jay Gupta
3:50-4:05	History of the “3 reviewer” requirement	Dr. Nathan Fountain
4:05-4:25	When does the “3 reviewer” requirement make sense?	Dr. Ben Brinkmann
	Case Examples	
4:25-4:35	Example 1: Reviewer requirement by technology	Epitel
4:35-4:45	Example 2: Reviewer requirement by type of seizure	Group discussion
4:45-5:30	Proposals for assessing ground truth for seizure annotation	

6:00 – 8:00 Reception & Networking