AGENDA

April 25 and 26, 2024

2024 Research Roundtable for Epilepsy

Drug development to address non-seizure outcomes associated with epilepsy

Meeting Objectives:

- Define how to evaluate that a therapy demonstrates benefits on non-seizure symptoms associated with epilepsy
- Outline existing and potential measures of co-morbidities in DEEs
- Propose methods for measuring seizure outcomes in disease modifying trials.

DAY 1 – Thursday, April 25, 2024

9:00 – 9:40	**Meeting Welcome & Updates**	
9:00 – 9:10	Welcome, Meeting Goals, and Deliverables	Dr. Caitlin Grzeskowiak, Bernice Lee
9:10 – 9:15	Updates on Previous RRE Topic	Drs. Jacqueline French and Nathan Fountain
9:15 – 9:40	Electronic seizure diaries	Michelle Campbell
9:40 – 9:55	**2024 Challenge and Overview**	
	Topic introduction	Drs. Jacqueline French and Nathan Fountain
9:55 – 10:25	**Natural history study partnerships** TSC Alliance	
9:55 – 10:05	International SCN8A Alliance	Gabi Conecker
10:05 – 10:15	TSC Alliance	Elizabeth Cassidy Sean Shillinger

10:15 – 10:25	Discussion	
10:25 – 10:40	**BREAK**	
10:40 – 11:55	**Session I: How to evaluate that a therapy demonstrates benefits on non-seizure symptoms associated with epilepsy**	
10:40-10:55	FDA Preliminary Comments	Dr. Paul Lee
	Treating seizures and non-seizure symptoms in epilepsy	
10:55 – 11:05	Example: Small molecule for rare epilepsy	Dr. Rima Nabbout
11:05 – 11:15	Example: Gene-targeted therapy for monogenetic diseases (ASO, gene, cell therapy)	Dr. Jackie Gofshteyn
11:15-11:55	Open Discussion	
11:55-12:55	**LUNCH**	
12:55 – 3:00	**Session II: Measuring a co-morbidities in DEE**	
12:55-1:15	FDA Landscape talk	Dr. Michelle Campbell
1:15-1:35	How much can you measure accurately with a variable baseline?	Dr. Madison Berl
1:35-1:55	Perspectives from the lived experience	Dr. Yssa DeWoody, Gabi Conecker
1:55 – 2:10	Industry perspective on measuring heterogeneity in drug development	Dr. Ebony Dashiell-Aje
2:10-3:00	Open Discussion	

3:00 – 3:15	**BREAK**	
3:15 –5:00	**Session III: Handling variability in manifestation of a disease and/or endpoint selection consideration**	
3:15 – 3:30pm	Varability in syndromes from natural history studies	Dr. Jillian McKee Dr. Ingo Helbig
3:30 – 3:50	Considerations for using an outcome measure that captures multiple aspects of DEE	Dr. Elizabeth Berry Kravis
3:50 – 4:10	Use of validated scales in a new indication	Dr. Xavier Liogier d'Ardhuy
4:10 – 4:20	FDA reflection	FDA
4:20-5 PM	Discussion	

DAY 2 – Friday, April 26, 2024

8:30 – 9:50	**Session IV: Measuring co-morbidity in adult epilepsy**	
8:30 – 8:35	Perspective from the lived experience	Brenda Sonneveldt
8:35 – 8:55	Measurement of memory in adults with TLE	Dr. Kim Meador
8:55 – 9:15	Measurement of mood in adults with TLE	Dr. Andy Kanner
9:15 – 9:50	Discussion	
9:50 – 10:45	**Session IV Conclusions of Main Agenda**	

9:50-10:45	Conclusions Discussion	
10:45 – 11:00	**BREAK**	
11:00– 12:15	**Session V: Hot Topic: Measuring seizure outcomes for disease modifying trials**	
11:00 – 11:15	Perspectives from the lived experience: Issues in seizure counting in long-term and DEE trials & what seizure outcomes are meaningful	Dr. Yssa DeWoody, Brenda Sonneveldt
11:15 – 11:30	Assessing uncountable seizures	Dr. Stephane Auvin
11:30 – 11:45	Discussion	
11:45 – 12:00	Maintaining long-term seizure diaries	Dr. Daniel Friedman & Dr. Gail Farfel
12:00 – 12:15	Discussion	
12:15 – 1:15	**LUNCH**	
1:15 – 2:15	**Session V Continued: Hot Topic: Measuring seizure outcomes for disease modifying trials**	
1:15 – 1:30	Seizure assessment when seizures are not the primary symptom	Dr. Sudha Kessler
1:30 - 2:00	Discussion	
2:00 – 2:15	Wrap Up & Conclusions	