AGENDA

2026 Research Roundtable for Epilepsy:
Innovative Trial Design and Other Control Arms to Reduce Placebo
April 30 – May 1, 2026

Meeting Objectives:

- Discuss the benefits and consequences of placebo add-on.
- Evaluate the feasibility of alternate trial designs.
- Assess strategies to reduce placebo responder rate.
- Explore when it may be appropriate to do an epilepsy trial that requires withdrawal of an ASM

DAY 1 – Thursday, April 30, 2026

8:00 am	**REGISTRATION and BREAKFAST**	
9:00 – 9:05 am	Welcome remarks – Innovation at the Epilepsy Foundation	Caitlin Grzeskowiak
9:05 – 9:15 am	Meeting goals, deliverables, and impact	Caitlin Grzeskowiak, Nathan Fountain & Billy Dunn
9:15 – 9:30 am	2026 challenge and topic overview	Jacqueline French
9:30 am – 12:05 pm	**Session I: Alternative trial designs** (Master protocol trials & adaptive designs)	
9:30 – 9:40 am	Lived experience	Veronica Hood
9:40 – 10:00 am	Alternative trial designs for rare diseases (N of 1, crossover trials, adaptive)	Kette Valente
10:00 – 10:20 am	Important considerations for trial design	Frank Harrell

10:20 – 10:40 am	Master protocol studies (platform trials, basket trials, umbrella trial)	Jason Connor
10:40 – 10:55 am	**BREAK**	
10:55 – 11:10 am	Shortening trials when absence of drug tolerance has been demonstrated	Farhad Sahebkar
11:10 – 11:20 am	FDA reflections	
11:20 am – 12:05 pm	Open discussion	
12:05 – 1:05 pm	**LUNCH**	
1:05 – 4:10 pm	**Session II: Alternative controls (natural history or active)**	
1:05 – 1:20 pm	Community-generated natural history data	Vanessa Vogel-Farley
1:20 – 1:35 pm	Natural history contributions	Kimberly Parkerson
1:35 – 1:50 pm	Looking for Lazarus	Ingo Hebig
1:50 – 2:25 pm	Open discussion	
2:25 – 2:40 pm	**BREAK**	
2:40 – 2:55 pm	Customary care add-on studies for adults	Nathan Fountain
2:55 – 3:10 pm	Customary care add-on studies for pediatrics	Dennis Dlugos

3:10 – 3:25 pm	Customary care in pediatric disorders with primary and secondary epilepsy elements	Christine Coquery
3:25 – 3:35 pm	FDA reflections	
3:35 – 4:10 pm	Open discussion	
4:10 – 4:25 pm	**BREAK**	
4:25 – 5:30 pm	**Session III: Reducing sample size** (via enrollment criteria, enrichment, single arm lead-in)	
4:25 – 4:45 pm	Variability in add-on trials: Where does it come from and what to do about it?	Wesley Kerr
4:45 – 4:55 pm	FDA reflections	
4:55 – 5:30 pm	Open discussion	
6:00 – 8:00 pm	**RECEPTION**	

DAY 2 – Friday, May 1, 2026

7:30 am	**BREAKFAST**	
8:30 – 10:30 am	**Session IV: Reducing placebo response**	
8:30 – 8:35 am	Stage setting	Nathan Fountain
8:35 – 8:45 am	Lived experience	Michelle Theeuwes
8:45 – 9:00 am	Where does the placebo responder rate come from?	Jacqueline French
9:00 – 9:45 am	Panel: How can we exclude subjects who are likely to have a high placebo responder rate?	Peter Forgacs, Wesley Kerr, Michael Panzara & Konrad Werhahn
9:45 – 9:55 am	FDA reflections	
9:55 – 10:30 am	Open discussion	
10:30 – 10:45 am	**BREAK**	
10:45 am – 12:35 pm	**Session V: When is it appropriate to do epilepsy studies that involve withdrawal of an anti-seizure medication (ASM)?**	
10:45 – 10:50 am	Stage setting	Jacqueline French
10:50 – 10:55 am	Experiences from the Dravet community	Veronica Hood

10:55 – 11:05 am	Lived experience	Carol & Dana Giordano
11:05 – 11:20 am	Risks of ASM withdrawal	Kate Davis
11:20 – 11:35 am	Trial designs that involve withdrawal: Are they appropriate for epilepsy?	Sam Terman
11:35 – 11:50 am	Phase II trials with no open label extension	Dan Friedman
11:50 am – 12:00 pm	FDA reflections	
12:00 pm – 12:35 pm	Open discussion	
12:35 – 1:20 pm	**LUNCH**	
1:20 – 2:00 pm	**Wrap up**	