Research Roundtable in the Epilepsies I: Reducing Placebo Exposure in Epilepsy Trials

May 19-20, 2016
Melrose Hotel
Washington, DC

Day One: May 19, 2016

12:30 PM	**Registration open** *[Potomac Room]*
1:00 PM	Welcome (Brandy Fureman, PhD, Vice President, Research & New Therapies and Phil Gattone, President and CEO Epilepsy Foundation)
1:15 PM	Meeting goals and deliverables (Nathan Fountain, MD, Research Roundtable Co-Chair and Jackie French, MD, Research Roundtable Co-Chair and CSO Epilepsy Foundation)

Background

1:30 PM	**Session I: Why is placebo control important?**
1:30 PM	Review basis of current phase III AED trial design (Tracy Glauser, MD)
1:45 PM	Active-control studies – loss of interpretability (Michel Baulac, MD)
2:45 PM	Open discussion
3:00 PM	**Session II: Why limit placebo exposure in epilepsy trials?**
3:00 PM	Increased SUDEP rate in placebo arm of studies of efficacious AEDs (Dan Friedman, MD)
3:15 PM	Reasons to limit placebo exposure (Jackie French, MD)
3:30 PM	Reasons to maintain placebo exposure (Nathan Fountain, MD)
3:45 PM	**Break**
4:00 PM	Enrollment considerations from participants' perspectives (Tracy Dixon Salazar, PhD)
4:15 PM	Remarks on ethics of add-on placebo (Jonathan Moreno, PhD)
4:30 PM	Open discussion
5:15 PM	**End of Day One**
6:00 PM	**Reception** *[William Penn Room]*
7:00 PM	**Dinner** *[Potomac Room]*

Day Two: May 20, 2016

7:00 AM **Breakfast** *[William Penn & Clifton Rooms]*

8:00 AM **Meeting start** *[Potomac Room]*

Phase III Design Proposals

8:00 AM **Session III: What Phase III design proposals can we consider?**
8:05 AM Proposal 1: Time to event designs (Emilia Bagiella, PhD)
8: 35 AM Discussion

9:15 AM Proposal 2: Placebo-control add on to standard of care (Nathan Fountain, MD)
9:30 AM Discussion

10: 00 AM **Break (and check-out)**

10:30 AM Proposal 3: Adaptive Bayesian design (Jason Conner, PhD)
11:00 AM Discussion

12:00 PM **Lunch** *[William Penn & Clifton Rooms]*

1:00 PM Proposal 4: Pooled placebo control (Jason Conner, PhD)
1:30 PM Discussion

2:10 PM Proposal 5: Separate trial designs for efficacy and safety (Jim Ferry, PhD)
2:40 PM Discussion

3:30 PM Proposal 6: Shorter trials when tolerance has been ruled out by prior trials (Jackie French, MD)
3:50 PM Discussion

4:15 PM Discussion of all proposals and recommendations
4:50 PM Conclusions

5:00 PM **Adjourn**