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