2017 Research Roundtable for Epilepsy
Pediatric Drug Development: moving toward a framework for antiepileptic drug use in children

March 2-3, 2017
American Institute of Architects
Washington, DC

Day One: Thursday, March 2, 2017

11:30 AM  Shuttle from W Hotel to AIA

12:30 PM  Registration open (AIA, Social Gallery outside Boardroom)

1:00 PM  Welcome (Dr. Brandy Fureman and Mr. Phil Gattone)
1:10 PM  Meeting goals and deliverables (Dr. Nathan Fountain and Dr. Jacqueline French)

1:20 PM  Regulatory pathways for pediatric approvals in the United States (Dr. Phil Sheridan)

1:40 PM  Regulatory pathways for pediatric approvals in Europe (Dr. Peter Karolyi and Dr. Syvie Benchetrit)

2:00 PM  Session I: Current landscape of pediatric epilepsy trials
2:05 PM  Talk 1: What requests are companies currently receiving? (Dr. Brandy Fureman)

2:20 PM  Talk 2: Is there a framework that can help determine what information about a new therapy is most useful to clinicians to apply in a given syndrome or seizure type, and that could be requested to complete a pediatric package? (Dr. Dennis Dlugos)

2:40 PM  Discussion
Day One: Thursday, March 2, 2017 (continued)

3:10 PM  Session II: At what age can syndromes and seizure types be diagnosed?

3:10 PM  Talk 3: Focal Seizures and primary generalized tonic clonic seizures (Dr. Kelly Knupp)

3:30 PM  Panel 1 discussion (Panelists: Dr. Elaine Wirrell, Dr. Dennis Dlugos, Dr. Alexis Arzimanoglou, Dr. Elizabeth Garofalo, Dr. Allen Hauser)

3:55 PM  Break

4:10 PM  Talk 4: Lennox-Gastaut Syndrome and Dravet Syndrome (Dr. Alexis Arzimanoglou)

4:30 PM  Panel 2 discussion (Panelists: Dr. Eric Marsh, Dr. Kelly Knupp, Dr. Elizabeth Thiele, Dr. Martina Bebin)

5:00 PM  Open discussion

5:25 PM  End of Day One (Shuttle returning to W Hotel)

6:00 PM  Reception (W Hotel, Altitude Foyer and POV Terrace)

7:00 PM  Dinner (W Hotel, Altitude Restaurant)
Day Two: Friday, March 3, 2017

7:15 AM    Shuttle leaving W Hotel for AIA (attendees should consider checking out and bringing luggage at this time)

8:00 AM    Breakfast (AIA Social Gallery)

9:00 AM    Meeting start (AIA Boardroom)

9:05 AM    Session III: The rationale for extrapolation
Talk 5 - Introduction to the rationale for extrapolation in focal seizures / PEACE (Dr. O’Neill D’Cruz and Dr. Joga Gobburu)

9:20 AM    Talk 6: Extrapolation to children with idiopathic generalized epilepsy with PGTCs (Dr. Allen Hauser)

9:40 AM    Panel 3: Does data exist to justify further use of extrapolation in other scenarios? Moderator: Dr. Dennis Dlugos
Panelists: Dr. Kelly Knupp, Dr. Alexis Arzimanoglou, Dr. Elizabeth Garofalo, Dr. Alan Hauser

10:10 AM   Session IV: Discussion of optimal trial designs for infant/young child studies
Moderator: Dr. Jacqueline French

11:00 AM   Break
Day Two: Friday, March 3, 2017 (continued)

11:15 AM   Session V: Indications for multiple seizure types in specific diseases or syndromes

11:15 AM   Talk 7: Pediatric syndromes with multiple seizure manifestations (Dr. Elizabeth Thiele)

11:35 AM   Panel 4 discussion (Panelists: Dr. Elizabeth Garofalo, Dr. Alexis Arzimanoglou, Dr. Dennis Dlugos, Dr. Elaine Wirrell, Dr. Martina Bebin)

12:05 PM   Open discussion

12:45 PM   Lunch (AIA Social Gallery)

1:30 PM   Session VI: Combined outcome measures in pediatric trials

1:30 PM   Talk 8: What are the appropriate outcome measures in pediatric trials? What about combined outcome measures? (Dr. Elaine Wirrell)

1:55 PM   Discussion

2:30 PM   Panel 5: How do the preferences of people with epilepsy and caregivers factor into the choice of outcome measures?

(Panelists: Ms. Nicole Villas [Dravet Syndrome Foundation], Mr. Steve Roberts [TS Alliance]; Dr. Tracy Dixon-Salazar [Lennox-Gastaut Syndrome Foundation])

2:50 PM   Discussion

3:30 PM   Conclusions and Next steps

4:00 PM   Adjourn