



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*)



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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

1:35PM 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 Roberds [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