



## 2020 Research Roundtable for Epilepsy (RRE)

*“Infantile seizure and innovative data capture, including electronic seizure diaries”*  
May 14-15, 2020

The 2020 RRE went virtual on May 14-15, convening researchers, people living with epilepsy, 22 drug and device companies and regulators from the FDA and others for discussions. There were two topics this year. The first was “Approval for focal epilepsy drugs for infants” and the other was “Innovative data capture, including electronic seizure diaries.”

At present, anti-seizure medications (ASMs) approved for focal epilepsy in adults can have efficacy from those trials extrapolated to the age 2 years, and can receive FDA approval with addition of only safety and pharmacokinetic data. Regarding infantile seizures, a major question is whether they are a separate entity analogous to the way neonatal seizures are a separate entity, or do infants have focal seizures that are similar to older age groups. And if they exist in a similar fashion, can data from older age groups also be extrapolated down to the 1 month to 2-year population to inform treatment choices. Pediatric epileptologists and researchers shared data demonstrating that the clinical picture of the way focal seizures begin and evolve, their characteristics and symptoms, EEG features and treatment response are similar to that of older children. These data support the possibility that no separate efficacy trials (which would be very difficult to accomplish) would be needed for these young children. In these circumstances, evidence of safety would need to be independently established in the infant age group and could not be extrapolated. If efficacy extrapolation is not possible, there are potential clinical trial designs to reduce or eliminate the need for a placebo group (where a person participating in the trial receives only the standard of care treatment, rather than the experimental treatment plus standard of care, and may experience a worsening of their seizures), for example a PK/PD design.

The group discussed special safety issues in children. The risks of evolution from focal seizures to infantile spasms and other seizure types or syndromes cannot be discounted, although to date there is no indication that specific drugs increase this risk. Cognition is a safety issue of particular importance in infants.

The second part of the meeting focused on electronic seizure diaries: their current use in clinical trials, barriers to completion, and possible alternatives or options to broaden their use. Regulators recommend that sponsors engage with the agencies early in development to discuss options for electronic seizure diaries. People living with epilepsy and caregivers shared their experiences, including their preference for a longer window for completion of seizure documentation (up to a week after the event, rather than the typical 1-2 days), and their reasoning for using various tracking tools such as spreadsheets rather than a particular digital diary tool. Industry members expressed willingness to collaborate to explore the potential of a standardized, more user-friendly seizure diary option.