

2021 Research Roundtable for Epilepsy (RRE)

*Seizure types and epilepsy syndromes: opportunity or obstacle?
April 8th and 9th, 2021*

The Research Roundtable for Epilepsy (RRE) is an initiative of the Epilepsy Foundation to facilitate the development and implementation of new treatments and diagnostic tools for people with epilepsy, by collectively addressing roadblocks to research and development. Each roundtable focuses on a single critical issue and allows an in-depth discussion in a pre-competitive space.

The 2021 RRE was again virtual, taking place on April 8th and 9th, convening researchers, caregivers of people living with epilepsy, 31 drug and device companies and regulators from the FDA and others for discussions. The topic this year focused on whether to group patients based on seizure types, epilepsy syndromes, or etiologies. Discussions revolved around potential opportunities to improve stratification and drawbacks to different approaches.

Goals of RRE 2021

The overall objective was to discuss how best to group epilepsy patients in clinical trials to ensure the results are generalizable to typical patients with epilepsy.

Specific discussions included:

- Syndromes vs. Seizures Therapeutic Approaches
- Seizure Types – Pathology and Physiology
- Considerations for Treating Syndromes
- Epidemiology, Clinical Presentation, and Treatment Responsiveness
- Considerations for Trial Design

Outcomes of RRE 2021

Based on roundtable discussions of these considerations, there was consensus that grouping as well as splitting seizure types in clinical trial design and/or treatment may be considered so long as there are clearly established principles based on mechanistic understanding, when known, to support the approach for a particular disease and/or treatment.

Conclusions

- Currently there are varied approaches when selecting populations for epilepsy regulatory trials. For example, for some indications certain seizure types are selected within a syndrome (ex. drop seizures in LGS) and in other indications all seizure types are counted (ex. focal seizures regardless of etiology).
- We need data to decide which syndromes (and seizure types) have patient populations that are homogeneous and similarly responsive to treatment.
- Basket trials are a trial design which could be explored further to expand the potential populations that are studied for efficacy, but noting there are specific

limitations based on various design considerations, including issues associated with analytical methods.

- Basic research is needed on biology of human seizure types and syndromes to determine physiologic similarities.

A manuscript is in preparation, and planning is already underway for an in-person RRE meeting in 2022, with the topic to be defined soon. Learn more about the RRE [here](#) or email Caitlin Grzeskowiak, Senior Director of Research and Innovation at cgrzeskowiak@efa.org.