



The  
**Epilepsy**  
Study Consortium

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# Mission

*A group of scientific investigators from academic medical research centers dedicated to accelerating the development of new therapies in epilepsy to improve patient care.*

*Our goals include:*

- *Building a partnership between academics, industry and regulatory agencies*
- *Optimizing clinical trial methodology in order to responsibly speed new treatments to patients.*



# ICARE Member Report: Epilepsy Study Consortium

- Types of research support or other activities
  - Standardized case report forms
  - Source documentation forms
  - Seizure diaries
  - Seizure classification training video
  - Standardized Inclusion/exclusion criteria
  - Seizure identification forms and Diagnostic Review Forms for ensuring appropriateness of enrolled subjects

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- Resources available for shared use or other opportunities for collaboration
  - Everything noted above
  - Available network of sites for trial implementation



# Three main activities

- # 1:
  - Conduct small, targeted “boutique” and proof of concept studies, through a variety of funding sources
    - Photosensitivity (Funded by Epilepsy Research Foundation)
    - Suicidality (Funded by Epilepsy Study Consortium)
    - Anti-inflammatory (Funded by Vertex Pharmaceuticals)
- # 2:
  - Assist the private, academic and public sectors in trial methodology, performance, and FDA interaction to increase the likelihood of a successful trial



# Three main activities

- # 3 (new):
  - Coordinate 20 centers in US and 20 in Europe who are expert at clinical trials, who can recruit for trials and ensure proper patient inclusion and trial conduct
  - This is increasingly necessary, as globalization of trials has led to inclusion of investigational sites that lack epilepsy expertise, potentially endangering ability of trials to succeed.



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- Priorities and/or plans for future activities
  - Design, test and implement novel trial designs to improve recruitment
  - Work with regulatory authorities (FDA, EMA) to optimize trial methodology
  - Create a standardized form for interviewing patients
  - AED XII conference 2013, Aventura Florida-conference focusing on issues related to antiepileptic drug development from preclinical discoveries through clinical evaluations.
    - This symposium is attended by representatives from academia, industry, the NIH, and the FDA to review what has been learned and to discuss strategies to enhance AED development. Includes presentations of drugs and devices in Preclinical /Phase I development and Later Stage Pipeline.



- The Epilepsy Study Consortium can increase the likelihood of successful trials and of new therapies advancing into pivotal regulatory trials
- This type of partnership is crucial to the future success of new therapeutic endeavors.