

ICARE Member Reports

- *Food and Drug Administration*
- To regulate research with investigational drugs (and some already marketed drugs) to ensure:
 - Safety (to the extent possible)
 - Trials are adequately designed to address the questions asked
- To review applications and to approve those treatments shown to be safe and effective

ICARE Member Reports: FDA

- ***Major topics of interest in epilepsy research***
 - To design trials to establish effectiveness as monotherapy
 - To investigate the safety and effectiveness of generic AEDs
 - To explore novel study designs in infants
 - To explore more efficient routes to the development of AEDs
 - Explore designs for “prevention” trials
- ***Types of research support or other activities***
 - Orphan product program
 - Frequent interactions with industry
 - Frequent participation in meetings with industry/academics

ICARE Member Reports: FDA

- *Priorities for future activities*
 - Issue guidance for monotherapy studies
 - Train new reviewers
 - Explore ways to develop treatments for Orphan syndromes