



## FDA Update, Pharmacology

### FDA Update: Anti-epileptic drug efficacy in adults can be extrapolated to pediatric patients

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Expansion of the indication for anti-epileptic drugs to pediatric patients with partial onset seizure (POS) frequently follows adult approval and typically is supported by at least one adequate and well-controlled clinical trial in the pediatric population. A number of anti-epileptic drugs now have a pediatric indication based on clinical efficacy trial data.

To determine whether a clinical efficacy trial is needed to label a drug for pediatric patients with POS, the Food and Drug Administration (FDA) led a critical path research initiative in collaboration with the University of Maryland and the Pediatric Epilepsy Academic Consortium for Extrapolation (PEACE). Investigators screened all approved anti-epileptic drugs to identify those having efficacy clinical trials in both adult and pediatric patients with POS, the most common type of seizure disorder in pediatric patients. Then, they conducted quantitative exposure-response analyses using datasets from the FDA and pharmaceutical companies.

The FDA concluded that the efficacy for anti-epileptic drugs can be extrapolated from successful adult efficacy trials to pediatric patients 4 years and older with POS. This determination was based on the similarity of POS in pediatric patients 4 years of age and older and adults and on the analysis of multiple drugs, which demonstrated a similar exposure-response relationship in pediatric and adult patients with POS.

This means that independent pediatric efficacy trials will not be needed for an anti-epileptic drug that has been approved to treat POS in adults when the drug's pharmacokinetic analysis shows that a dosing regimen provides similar drug exposure (at levels demonstrated to be effective in adults) in pediatric patients 4 years of age and older and in adult patients with POS. Efficacy trials still are needed for children younger than 4 years of age, and a long-term, open-label safety study(ies) in pediatric patients 4 years of age and older is still necessary.

#### Resource

Dunne J, et al. "Extrapolation of Adult Data and Other Data in Pediatric Drug-Development Programs," [Pediatrics. 2011;128:e1242-e1249](#) .

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