Clinical studies primarily assess the efficacy of an antiepileptic drug (AED) based on group change in seizure frequency and responder analyses, but the level of seizure reduction or change in frequency is generally considered meaningful if it is greater than 30%. A ≥50% reduction in seizure frequency is generally considered meaningful and was used in our study. ROC analysis can be used to define a “clinically meaningful” threshold (CMPT) and evaluate the diagnostic properties of the CGI-I rating. Our post hoc analysis of pooled data from Study 1 (NCT02682927, NCT02826863), a randomized, double-blind, placebo-controlled study of oral sodium in fenfluramine (FFA) 0.5 mg/kg/day FFA, or placebo for the treatment of GEFS+, clinicogenic seizure frequency was assessed for month 12 (Visit 12) in 114 patients aged 12-36 years enrolled in Study 1. CGI-I ratings were provided by the caregivers (A) or investigators (B). The ROC curve illustrates the diagnostic properties of the CGI-I rating. We used 44% reduction in monthly convulsive seizure frequency (MCSF) relative to placebo as our CMPT to identify responders. Table 1 presents the ROC analysis using the CMPT of ≥44% reduction in MCSF. The Area Under the Curve (AUC) for the CGI-I rating by investigator was 0.815 (0.769, 0.918). Receiver operating characteristic (ROC) analysis of the pooled data with “Much Improved” vs “Minimally Improved” or worse identified a 44% reduction in MCSF as the cutpoint for a clinically meaningful change, with a sensitivity of 0.875 or a specificity of 0.815. The clinically meaningful threshold was defined as the cutpoint where specificity = sensitivity, or 0.875. Using the 44% reduction in MCSF as the threshold, 75%, 46%, and 13% of patients in the FFA arm were classified as “Very Much Improved” or “Much Improved” (Table 1). Figure 2 illustrates the ROC curve for the CGI-I rating by investigator, with a sensitivity of 0.875 and a specificity of 0.815. Figure 3 illustrates the ROC curve for the CGI-I rating by caregiver, with a sensitivity of 0.875 and a specificity of 0.815. Additional information is available in the full manuscript, which can be accessed through the provided link.