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**THE PHILIPPINE STATISTICIAN**  
**2007, Volume 56, Nos. 1-2**

**The Design and Analysis of Pivotal Clinical Trials To Assess  
the Efficacy of Drugs to Treat Panic Disorder**

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**Abstract**

US Federal Regulations require at least two pivotal proofs of efficacy clinical trials (typically Phase III) to support approval of a drug for a specific indication. In the clinical development of drugs to treat panic disorder, one of these trials may incorporate a forced titration design while the other may incorporate a flexible titration - according to response design. Standard analysis approaches include treatment group comparisons at each follow-up visit in terms of variables reflecting domains of the panic condition. Such designs pose challenges as to: (1) characterizing the dose response profile across both studies; (2) characterizing duration of effect; (3) characterizing withdrawal effects; and (4) the choice of appropriate statistical analysis methods. Standard approaches to meeting these challenges, as well as reasonable alternatives are presented.

**Keywords:** *Pivotal, Clinical Trials, Panic Disorder, Duration of Effect, Withdrawals*