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**Statistical Analysis Methods for Providing Inferences between  
Primary Response Measures and Exposure to Study  
Medication**

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**Abstract**

Differential exposure to study medications in long-term studies of drugs complicates analyses of and inferences from the data collected, particularly with respect to the usual intention-to treat population. Analysis methods which incorporate exposure are developed, presented and illustrated by applying them to primary response data from a long term, placebo controlled, clinical trial of gemfibrozil (the Primary Helsinki Heart Study). The analysis methods address the extent to which endpoints are correlated with the actual use of the compound rather than the extent to which endpoints are correlated with the random assignment to double-blind study medications.

**Keywords:** *Exposure Analysis, Long-term CHD Studies, Intent-to-Treat*