



TITLE: Using R and BRugs in Bayesian Clinical Trial Design and Analysis

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TIME: 1:00 P.M. **(NOTE DIFFERENT TIME)**

DATE: Tuesday, March 7, 2006 **(NOTE DIFFERENT DAY)**

ROOM: 133 SMI **(NOTE DIFFERENT ROOM)**

ABSTRACT:

Thanks in large part to the rapid development of Markov chain Monte Carlo (MCMC) methods and software for their implementation, Bayesian methods have become ubiquitous in modern biostatistical analysis. In submissions to the U.S. FDA Center for Devices and Radiological Health, where data on new devices are often scanty but researchers typically have access to large historical databases, Bayesian methods have been in common use for over a decade. However, statisticians and regulators on the drug side of FDA are also now coming to appreciate the value of these methods, especially their ability to combine information from separate but related sources, reduce sample size, and directly measure the effects of interest while protecting overall error rates.

This talk will review how a variety of Bayesian clinical trial design and analysis methods can be implemented in R and BRugs, the version of the OpenBUGS package callable from within R. In particular, we will illustrate how a Bayesian might think about "power" when designing a trial, and how a Bayesian procedure may be calibrated to guarantee good long-run frequentist performance (i.e., low Type I and II error rates), a subject of keen interest to the FDA. The presentation is intended to be accessible to a broad audience, and to generate discussion regarding areas requiring further development before Bayesian clinical trial design and analysis can be realistically considered for routine adoption by practitioners.