PUBLIC HEALTH & PREVENTIVE MEDICINE

GRAND ROUNDS

Co-Sponsored by Knight Cancer Institute Biostatistics Shared Resource & the Division of Biostatistics

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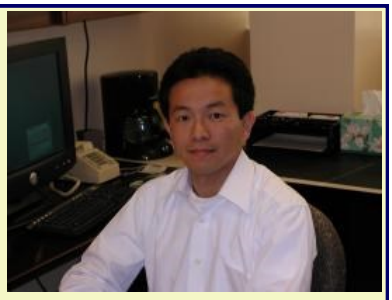

Thursday, December 19, 2013
12 PM-1 PM
Campus Services Building Room 679

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The prudent statistician's guide to two-stage designs

ABSTRACT

Unlike a conventional single-stage clinical trial, a good two-stage procedure is difficult to design even for a normally distributed endpoint with a known standard deviation. In addition to the usual type I and II errors, decisions must be made with regard to the timing of the interim analysis, size of the type I and II errors to spend in the first stage, and sample size for stage 2, which may not be constant with respect to stage 1 data. Moreover, the design must be in accordance with regulatory guidelines.

In this talk, Dr. Koyama will introduce a framework for two-stage clinical trials that encompasses many designs that satisfy the requirements set forth in the FDA's guidelines. Placing a number of designs under a uniform framework facilitates design comparison and makes it easier to suggest a prudent design in the absence of the optimal design.

Dr. Koyama will also introduce an approach for making inferences from a two-stage design. The framework is general and includes even Simon's design for phase II clinical trials with a binary endpoint. He will demonstrate how to compute a p-value, estimate the response rate, and derive a confidence interval for Simon's design such that they are consistent with the hypothesis testing.

This is a brown bag event. Please feel free to bring your own lunch to eat during the lecture.

For further information or questions about this event, please contact Tomi Mori: 503-418-1555 , morim@ohsu.edu

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