

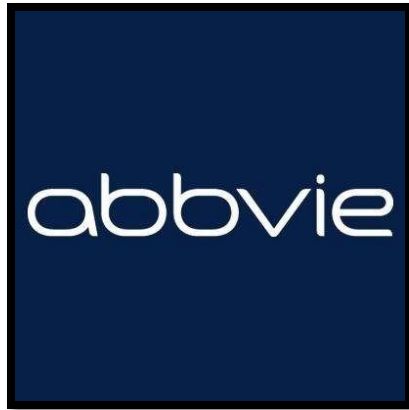
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# STATISTICS SEMINAR

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UW-Department of Statistics

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**Abstract:** Basket trial designs have grown steadily in popularity over the last 15 years in the context of phase 2 cancer clinical trials alongside widespread emergence of molecularly targeted anticancer agents. Targeted therapies are central to the paradigm of personalized medicine and leverage emerging insights into the biomolecular structure and drivers of cancer to suppress or kill tumors. The mechanism of action of these agents predominantly depend on the genetic signatures as opposed to histology. Basket designs provide a framework for testing these agents in molecularly defined cohorts across multiple tumor types with great efficiency. Design implementation, however, can vary considerably in flavor and the level of efficiency it seeks to gain. In its most versatile form, a basket design will allow synthesis of selected information across various subgroups of patients using fairly sophisticated Bayesian hierarchical models to draw more accurate inferences compared to traditional designs of similar sample-size. The earliest example of a Bayesian basket design using such information borrowing was published in 2003 by Thall and colleagues for a phase 2 trial of imatinib in multiple types of soft-tissue sarcomas. Recent publications have provided more examples and greater scrutiny of these designs, and thereby greater understanding of the pros and cons of such approaches.

In this talk I will discuss the design considerations for a real-life phase 2 cancer clinical trial in non-small cell lung cancer patients of telisotuzumab vedotin, a novel molecularly targeted antibody drug conjugate. Efficacy of the compound is expected to depend on both tumor histology as well as its level of c-Met expression. We plan to implement a basket design using a Bayesian hierarchical model in this setting allowing evidence synthesis under multifactorial exchangeability. Such implementation requires careful crafting of the Bayesian model and decision-rules to meet the demands of the study and the clinical development program. We also illustrate how prior efficacy information from phase 1 may be incorporated into the design.

**TITLE:** Design and Implementation of a Basket Trial Design using a Multifactor Bayesian Hierarchical Model

**Speaker:**

**Jyotirmoy Dey**

Director of Statistics at AbbVie Inc., and Statistics Therapeutic Area Head for Solid Tumor Development

**Time & Place:**

Wednesday,

October 2, 2019

**4:00**, Room 140

Bardeen

Cookies & Coffee @

**3:30**, Rm 1210 MSC

