

November 9, 2005

Colorado-Wyoming Chapter

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Title: Pearls of Wisdom Learned from Clinical Trials of a New Anticancer Therapy

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When: Wednesday, November 9, 2005 7:30 p.m.

*(coffee, tea and refreshments will be served at 7 p.m.)

Where: CU Denver Math Department - 1250 14th Street (at 14th and Larimer Street) - 6th floor - Denver.
(See details below for directions and parking.)

Talk Outline:

Tarceva? is a new, oral, anticancer agent. It is approved for the treatment of patients with non-small cell lung cancer after failure of at least 1 prior chemotherapy. Recently, the FDA asked its Oncologic Drugs Advisory Committee (ODAC) to review results of a randomized, double-blind, placebo-controlled clinical trial of Tarceva? in combination with standard chemotherapy (gemcitabine) for patients with untreated, advanced pancreatic cancer. During the preparation for the presentation to ODAC, several unusual statistical issues were encountered, including: - The optimal dose was not known at the beginning of the study, so two doses were evaluated in subsets of patients - The sample size was changed twice during the study Prior to unblinding, the FDA requested a change in the Statistical Analysis Plan and offered two options: either stratified log-rank test for survival or a univariate log-rank test - After unblinding, the FDA identified a subset of patients who were not technically eligible for the study - After unblinding, the FDA requested that follow-up information be updated

The impact of these issues on the interpretation of the study results and the trials and tribulations of estimating the treatment benefit will be discussed.

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Directions and Parking:

The seminar will be held at the CU- Denver Math Department in downtown Denver. Information about directions and parking can be found at <http://www-math.cudenver.edu/contact/map2office.html> . Metered parking may be available for up to 2 hours on the street at a cost of \$1/ hour. Please note that there is a Denver Nuggets game that evening that will begin at 8:30. This can impact parking. Security: After 7pm, access to the 6th floor requires an access key> for the elevator. When you are signing in at the front desk, please ask the security guard to activate the elevator for you.