The September 2010 Meeting of the San Francisco Bay Area Chapter of the American Statistical Association (ASA)

Adverse Event Signal Detection: Overall Comparisons, Future Projections and False Discoveries

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AMGEN Inc.

Monday, September 13, 2010
Refreshments 4 – 4:30pm, Presentation 4:30 – 5:30pm

Amgen South San Francisco, Building 3 (ASF3), room 1019
1150 Veterans Blvd, South San Francisco, CA 94080

RSVP Required by 9/9/2010 Thu. & Bring ID for Security Check
Please email your name and affiliation to Jing Huang at AMGEN jihuang@amgen.com if you plan to attend.

Abstract

Signal detection of unexpected adverse events (AEs) in Phase 3 clinical trials is complicated by two conflicting facts: one is the high rate of false positive findings if the per comparison error rate is controlled, and the other is the high rate of false negative findings if a family wise error rate is controlled. Our proposal for detecting unexpected safety signals, intended for informal inference, is aimed at mitigating the influence of these high error rates. To illustrate the application of our method we apply it to real data. Limitations of the proposed method are discussed.

We propose the following:

(a) Visualization methods to help decide how to proceed with additional analyses.

(b) If visualization suggests further investigation, then we propose, for each AE, make future projections of the number of subjects with AEs based on a weighting scheme that involves an empirical Bayes perspective. Future projections are obtained as a weighted average of the rates projected under the null and alternative conditions. Such projections are relevant if the following question is of interest: “how many more subjects would experience the event if the trial duration is increased?”

(c) Flag AEs that are significant in the observed and projected portions of the trial after controlling the false discovery rate rather than a family-wise error rate. The new AEs flagged for the projected portion are additional AEs to pay attention to in making the risk-benefit assessment.

About Speakers

Jeetu Ganju Ph.D. is Director, Medical Sciences Biostatistics in AMGEN.
Jing Huang Ph.D. is Senior Manager, Medical Sciences Biostatistics in AMGEN
Julie Ma Ph.D. is Senior Manager in inflammation late development biostatistics group in AMGEN

Directions

AMGEN South San Francisco can be reached by car, BART or Caltrain. Here are the driving direction, shuttle

schedules from BART and Caltrain stations & the Amgen SSF campus map. Riders should hop-off at 1120 Veterans Blvd stop and walk to 1150 (i.e. building ASF3). Regarding parking, the participants can park anywhere in the open space parking lot near the building. We don't have specific reserved areas for visitors and usually there are plenty of space. But, do try NOT to park in the garage since that's reserved for Amgen employees.

Driving directions to AMGEN South San Francisco from www.mapquest.com:

From 101 SOUTH: Take the OYSTER POINT BLVD EAST exit, EXIT 425B. Turn SLIGHT RIGHT onto OYSTER POINT BLVD. Turn LEFT onto VETERANS BLVD. 1150 VETERANS BLVD is on the RIGHT.
From 101 NORTH: Take EXIT 425B toward OYSTER PT BLVD. Turn LEFT onto DUBUQUE AVE. Turn RIGHT onto OYSTER POINT BLVD. Turn LEFT onto VETERANS BLVD. 1150 VETERANS BLVD is on the RIGHT.
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