

For more information:

Rosanne Desmone
703.302.1861 (direct)
703.946.3820 (mobile)
Rosanne@amstat.org

American Statistical Association Announces Upcoming Webinars for Statisticians in Biopharmaceutical Industry

**November webinar viewed by more than 700;
registration currently open for December 7 and January 10 sessions**

ALEXANDRIA VA (PRWEB) NOVEMBER 29, 2007 – The American Statistical Association (ASA) has announced the schedule for the remaining sessions in its Fall series of webinars for statisticians working in the biopharmaceutical industry. The sessions are sponsored by ASA's Biopharmaceutical Section and are open to both ASA members and nonmembers. The November webinar was viewed by more than 700 individuals at 175 sites worldwide, including Canada, Europe, Australia, and China.

"We are very pleased with the amount of attention the webinar program has received," said Alex Dmitrienko, chair of Distance Training, Biopharmaceutical Section, and Research Advisor, Eli Lilly and Company. "The webinars have been 'attended' by industry and academic statisticians, statisticians working at government regulatory agencies and graduate students. We now are beginning to identify important biopharmaceutical topics and topic experts for the Spring 2008 training series and are excited about this opportunity to provide cost-effective training options to a broad audience of biostatisticians."

The topics, presenters, and dates of the final two Fall sessions are as follows:

- **December 7: Group-sequential Designs and Sample Size Adaptation**
Presenters: Cyrus Mehta, Cytel Statistical Software; Jon Denne, Eli Lilly and Company; and Keaven Anderson, Merck & Co.

The session will consider various strategies to right-size a trial by adapting with information observed in the trial. Methods considered include internal pilot studies, group sequential designs and conditional power methods. When it may be desirable and acceptable to use adaptation methods that employ unblinded data will be considered. A specific case-study will be used to demonstrate application of several of the strategies presented.

- **January 10: Seamless Adaptive Designs & Trial Integrity Issues for Adaptive Designs**
Presenters: Jeff Maca and Paul Gallo of Novartis Pharmaceuticals

The use of adaptive seamless designs is an innovative approach that enables the combining of traditionally separate studies into a single trial. This can allow for shorter times needed to reach registration, and more efficient use of clinical data and available resources. However, these types of designs present challenges, both statistical and logistical, which must be addressed in deciding if a given program is a good candidate for such a design, and in actual implementation of the design. This webinar will investigate the statistical approaches which can be used to design seamless trials, and will discuss the analysis methodology that can be used. The second part of the webinar will discuss some logistic and operational issues relevant to seamless designs, but which also apply more generally to any adaptive trials in a confirmatory setting. Particular emphasis will be given to processes for interim data

monitoring and decision making in adaptive trials, to limit access to the accruing results in order to maintain trial integrity. Several case studies will be presented to illustrate concepts discussed in the course.

Both sessions will run from Noon to 2 pm Eastern time. Complete information and online registration are available at <http://www.amstat.org/sections/sbiop/webinarseries.html>.

About the American Statistical Association

The American Statistical Association (ASA), a scientific and educational society founded in Boston in 1839, is the second oldest professional society in the United States. For more than 160 years, ASA has been providing its 18,000 members serving in academia, government, and industry and the public with up-to-date, useful information about statistics. The ASA has a proud tradition of service to statisticians, quantitative scientists, and users of statistics across a wealth of academic areas and applications. For additional information about the American Statistical Association, please visit the association's web site at <http://www.amstat.org> or call 703.684.1221.

#####