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Clinical Trials Are a Hot Topic at the Joint Statistical Meetings

The FDA, drug companies and academicians report on various aspects of clinical trials in many of the 2,500+ sessions at JSM in Denver August 3-7

ALEXANDRIA, VA (PRWEB) JULY 28, 2008 – Clinical trials are the focus of numerous sessions at the annual Joint Statistical Meetings (JSM), where statisticians from around the world will report on and discuss the statistical implications of topics in a number of fields, the American Statistical Association (ASA) said today. JSM, the world's largest annual gathering of statisticians, is attended by more than 5,000 statistics experts from government, industry and academia and features some 2,500 presentations, panels, roundtables and other sessions. JSM 2008 will be held at the Colorado Convention Center August 3—7.

“Clinical trials are the means by which companies and the FDA evaluate the safety and efficacy of new drugs, biologics, and devices,” said Peter A. Lachenbruch, ASA president. “Companies and the FDA use statistical methods for these evaluations. The JSM sessions will address issues regarding clinical trials in many specific areas, including safety, ophthalmic device trials, how to handle missing values, biomarkers, and vaccine evaluation.”

Some of the JSM sessions on the topic of clinical trials are described below; additional sessions on this subject can be found at

<http://www.amstat.org/meetings/jsm/2008/onlineprogram/index.cfm?fuseaction=main>, where you can search on keywords, presenter's name or affiliation. [Note: Members of the press can register for the conference online at

<http://www.amstat.org/meetings/jsm/2008/index.cfm?fuseaction=pressregistration>]

Safety Findings in Clinical Trials: Are They Real, or Just Coincidental? (Activity #522)

Presenters: Mani Lakshminarayanan, Merck & Co., Inc.; Amarjot Kaur, Merck & Co., Inc.

In all phases of clinical trials, the underlying risk of an investigational drug is determined based on number safety endpoints including adverse events, laboratory data, vital signs, electrocardiogram and others. Due to the inherent multiplicity in safety data, inferential procedures (if employed) tend to control false positive rates using procedures based on p-values. Most of these procedures are designed to control various types of error rates such as family-wise error rate or the false discovery rate. This paper examines the impact of small samples (Phase-II trials) as well as the correlation between safety endpoints on various measures that are outlined above.

http://www.amstat.org/meetings/jsm/2008/onlineprogram/index.cfm?fuseaction=abstract_details&abstractid=301414

A New Approach To Monitor the Safety Risk in Clinical Trials (Activity #522)

Presenters: Chenxiong (Charles) Le, MedImmune, Inc.; Qing Liu, Johnson & Johnson Pharmaceutical R&D, LLC

Monitoring safety risk is essential in clinical trials to protect patients and to reach decisions on dose selection. The traditional sequential probability ratio test (SPRT) is appropriate for short term safety endpoints, but it can be problematic when safety risk is monitored over a longer period of clinical evaluations. A new method, based on a reverse sampling, is proposed to monitor the safety risk, and the characteristics are investigated. This method is illustrated in an example in a large cardiovascular dose escalation study.

http://www.amstat.org/meetings/jsm/2008/onlineprogram/index.cfm?fuseaction=abstract_details&abstractid=300966

Statistical Considerations in Ophthalmic Device Trials (Activity #49)

Presenter: Hollington T.C. Lu, U.S. Food and Drug Administration

The eye has a wide variety of structures in which physical and functional defects can have serious consequences impacting the ability to perform in everyday life. There are many ophthalmic devices that have been developed in recent times for treating and managing eye diseases. For a biostatistician, the most important distinction between ophthalmologic data and data obtained in most other medical specialties is whether the information is collected on an eye-specific or subject-specific basis. The statistical issues and examples presented are the correlation of left and right eye, longitudinal nature of the ocular measurements, post-marketing study of longitudinal cell density and glaucoma diagnosis.

http://www.amstat.org/meetings/jsm/2008/onlineprogram/index.cfm?fuseaction=abstract_details&abstractid=300879

Analytical Issues and Practical Solutions for Missing Data in Clinical Trials (Activity #152)

Presenter: Jayawant Mandrekar, Mayo Clinic

Missing data is a reality in clinical trials, and the practical complexities associated with analysis of missing data need attention. A case study comprising a recently completed Phase III randomized, double-blinded, placebo-controlled trial will be used to motivate the discussion. Scientific rationale for the trial, the *a priori* assumptions used at the design stage, issues encountered due to unplanned proportions of missing data that led to revisions of the study design and endpoints, and the involvement of the regulatory and oversight committees will be the background for this discussion.

http://www.amstat.org/meetings/jsm/2008/onlineprogram/index.cfm?fuseaction=abstract_details&abstractid=300684

Study Designs for Biomarker-Based Treatment Selection (Activity #214)

Presenter: Amy Laird, University of Washington; Andrew Zhou, University of Washington

Among patients with the same clinical disease diagnosis, response to a treatment is often quite heterogeneous. For many diseases this may be due to molecular heterogeneity of the disease itself, which may be measured via a biomarker. In this talk, we consider the problem of evaluating clinical trial designs for drug response based on an assay of a predictive biomarker. We outline several marker validation trial designs in terms of the scientific questions each one is able to address, and compute the number of patients required for each one. We exhibit efficiency graphs for several special cases to summarize our results.

http://www.amstat.org/meetings/jsm/2008/onlineprogram/index.cfm?fuseaction=abstract_details&abstractid=300214

About JSM

JSM, the world's largest annual gathering of statisticians, is held jointly with the American Statistical Association (ASA), the International Biometric Society (ENAR and WNAR), the Institute of Mathematical Statistics (IMS), and the Statistical Society of Canada (SSC). The theme for this year's conference is *Communicating Statistics: Speaking Out and Reaching Out*. A brief history of the JSM can be found at <http://www.amstat.org/meetings/jsm/2008/pdfs/ABriefHistoryoftheASAAnnualMeetings.doc>.

About the American Statistical Association

The American Statistical Association (ASA), a scientific and educational society founded in Boston in 1839, is the second oldest continuously operating 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.

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