

FDA/Industry Statistical Workshop

Statistical Issues for the New Millennium

Preliminary Program

THURSDAY, September 30, 1999

8:00 a.m.-8:30 a.m. **Continental Breakfast**

8:30 a.m.-8:45 a.m. **Welcome and Housekeeping**

ASA/Biopharmaceutical Section Chair: **S. Snapinn**, Merck & Co.

FDASA President: **G. Campbell**, Food and Drug Administration

Workshop Co-Chairs: **R. Harkins**, Quintiles; **N. Smith**, Food and Drug Administration

8:45 a.m.-10:15 a.m. **Regulatory Roundtable - FDAMA and Beyond**

Organizer/Moderator: **N. Smith**, Food and Drug Administration

Statistical Leadership from several Centers of the FDA will discuss the role of statistics in our changing regulatory environment

10:15 a.m.-10:45 a.m. **Morning Break**

10:45 a.m.-12:15 p.m. **Interim Analysis and Data Safety Monitoring Boards**

Organizers: **R. Harkins**, Quintiles; **M. Huque**, Food and Drug Administration

Chair: **R. Harkins**, Quintiles

Speaker: *Interim Analysis and Data Monitoring*, **G. Chi**, Food and Drug Administration

Speaker: *DSMB, Problems and Solutions*, **S. Snapinn**, Merck & Co.

Speaker: *Interim Analysis*, **J. Lachin**, George Washington University

12:15 p.m.-1:30 p.m. **Lunch (on your own)**

1:30 p.m.-3:00 p.m. **Meta Analysis Applied to Non-Inferiority Trials**

Organizer: **H. Hsu**, Food and Drug Administration

Chair: **A. Lachenbruch**, Food and Drug Administration

Speaker: *Some Approaches for Meta-Analysis in Non-Inferiority Trials*, **A. Gould**, Merck

Speaker: *Issues on Meta-Analysis of Sepsis Trials*, **J. Wittes**, Statistics-Collaborate

Speaker: *Experience on Meta-Analysis of Cough-Cold Preparation*, **R. D'Agostino, Sr.**, Boston University

Discussant: **C. Anello**, Food and Drug Administration

3:00 p.m.-3:30 p.m. **Afternoon Break**

3:30 p.m.-5:00 p.m. **Multiple locations, inference space, mixed models, and their impact on design and analysis of experiments**

Organizers: **A. Nevius**, Food and Drug Administration; **J. Derr**, Food and Drug Administration

Chair: **A. Nevius**, Food and Drug Administration

Speaker: *An Academic Statistician's Perspective*, **W. Stroup**, University of Nebraska

Speaker: *An Industry Statistician's Perspective*, **A. Dayton**, Pfizer Animal Health

Speaker: *An FDA Statistician's Perspective*, **J. Gilbert**, Food and Drug Administration

5:00 p.m.-6:30 p.m. **Reception (Cash Bar)**

FRIDAY, October 1, 1999

8:30 a.m.-10:00 a.m. Three Simultaneous Sessions

Session 1: Use and Misuse of Covariance Analysis in Clinical Trials

Organizers: **K. Kazempour**, Amarex; **R. Harkins**, Quintiles

Chair: **K. Kazempour**, Amarex

Speaker: *We should Kill and Deal with the Known Covariates in Design Stage*, **S. Hedayat**, University of Chicago

Speaker: *Model - searching is dangerous but pre-specifying is robust*, **T. Permutt**, Food and Drug Administration

Speaker: *Analysis of Covariance and Surrogate Marker*, **A. Balch**, Searle Research and Development.

Session 2: Statistical Issues in Diagnostic Medical Products

Organizers: **H. Bushar**, Food and Drug Administration; **L. Makris**, BioCor

Chair: **J. Castellana**, Berlex Laboratories

Speaker: **D. Hawkins**, University of Minnesota

Speaker: *Measures of Agreement: Recent Advances and Future Directions*, **M. Donovan**, Covance

Speaker: *Discrepancy Resolution*, **K. Meier**, Food and Drug Administration

Session 3: Statistical and Interpretive Issues in Health Related Quality of Life Data

Organizers: **J. Zhang**, Merck Research Laboratories; **C. Gnecco**, Food and Drug Administration

Chair: **J. Zhang**, Merck Research Laboratories

Speaker: *Interpretation of changes and between group differences in HRQL*, **N. Santanello**, Merck Research Laboratories

Speaker: *An FDA Review Perspective on Statistical Design and Analytic Aspects for Studies with HRQOL Endpoints*, **C. Gnecco**, Food and Drug Administration

Speaker: *Biostatistical challenges created by quality of life research*, **I. Barofsky**, Johns Hopkins University School of Medicine

10:00 a.m.-10:30 a.m. Morning Break

10:30 a.m.-12 noon Three Simultaneous Sessions

Session 1: Some Approaches to Postmarketing Surveillance Safety Assessment

Organizers: **C. Anello**, Food and Drug Administration; **R. O'Neill**, Food and Drug Administration

Chair: **C. Anello**, Food and Drug Administration

Speaker: *Special Issues in Monitoring Vaccine Safety*, **S. Ellenberg**, Food and Drug Administration

Speaker: *Evaluating Methodologies for Analysis of ADRs in Marketed Products*, **S. McDermott**, Glaxo Wellcome

Speaker: *Assessing Gender effects from a large Spontaneous Reporting Data Base*, **A. Szarfman**, Food and Drug Administration

Discussant: **R. O'Neill**, Food and Drug Administration

Session 2: Perspectives in the Use of Bayesian Statistics in Clinical Trials

Organizers: **G. Campbell**, Food and Drug Administration; **K. Ghosh**, Merck

Speaker: *Statistical Analysis of Unexpected Events*, **R. Simon**, NCI

Speaker: *The Future of Bayesian Statistics in the Pharmaceutical Industry*, **A. Grieve**, Pfizer

Speaker: *Bayesian Methodology at the Center for Devices and Radiological Health-Past, Present and Perspectives for the Future*, **T. Irony**, Food and Drug Administration

Session 3: The Design and Analysis of Studies to Assess the Effect of Inhaled Steroids on Growth

Organizers: **A. Segreti**, Glaxo Wellcome, **S. Wilson**, Food and Drug Administration

Session Chair: **R. Liddle**, Glaxo Wellcome

Speaker: *Overview of Topic*, **Speaker TBA**

Speaker: *A Pharmaceutical Industry Perspective*, **S. Duke**, Glaxo Wellcome,

Speaker: *An FDA Perspective*, **B. Elashoff**, Food and Drug Administration

12:00 p.m.-1:15 p.m. Lunch (on your own)

FRIDAY, October 1, 1999 (continued)

1:15 p.m.-2:45 p.m. Issues in the Analysis of Data with Missing Values

Organizers: **R. Small**, Pfizer; **E. Nevius**, Food and Drug Administration

Chair: **R. Small**, Pfizer

Speaker: *Testing for treatment differences with dropouts present in clinical trials - a 'pattern but not mix' approach*, **W. J. Shih**, Merck & Co.

Speaker: *Missing Data - Does it matter?* **G. Tudor and V. Hasselblad**, Duke Clinical Research Institute

Speaker: TBA, Food and Drug Administration

2:45 p.m.-3:00 p.m. Closing and Evaluations

Workshop Co-Chairs: **N. Smith** and **R. Harkins**

Program Committee

Harry Bushar, Food and Drug Administration

Greg Campbell, Food and Drug Administration

Ralph Harkins, Quintiles

Sandy Heft, Schering Plough

Henry Hsu, Food and Drug Administration

Lukas Makris, BioCor

Anna Nevius, Food and Drug Administration

Bob O'Neill, Food and Drug Administration

Tony Segretti, Glaxo Wellcome

Robert Small, Pfizer

Nancy Smith, Food and Drug Administration

Ji Zhang, Merck & Co.