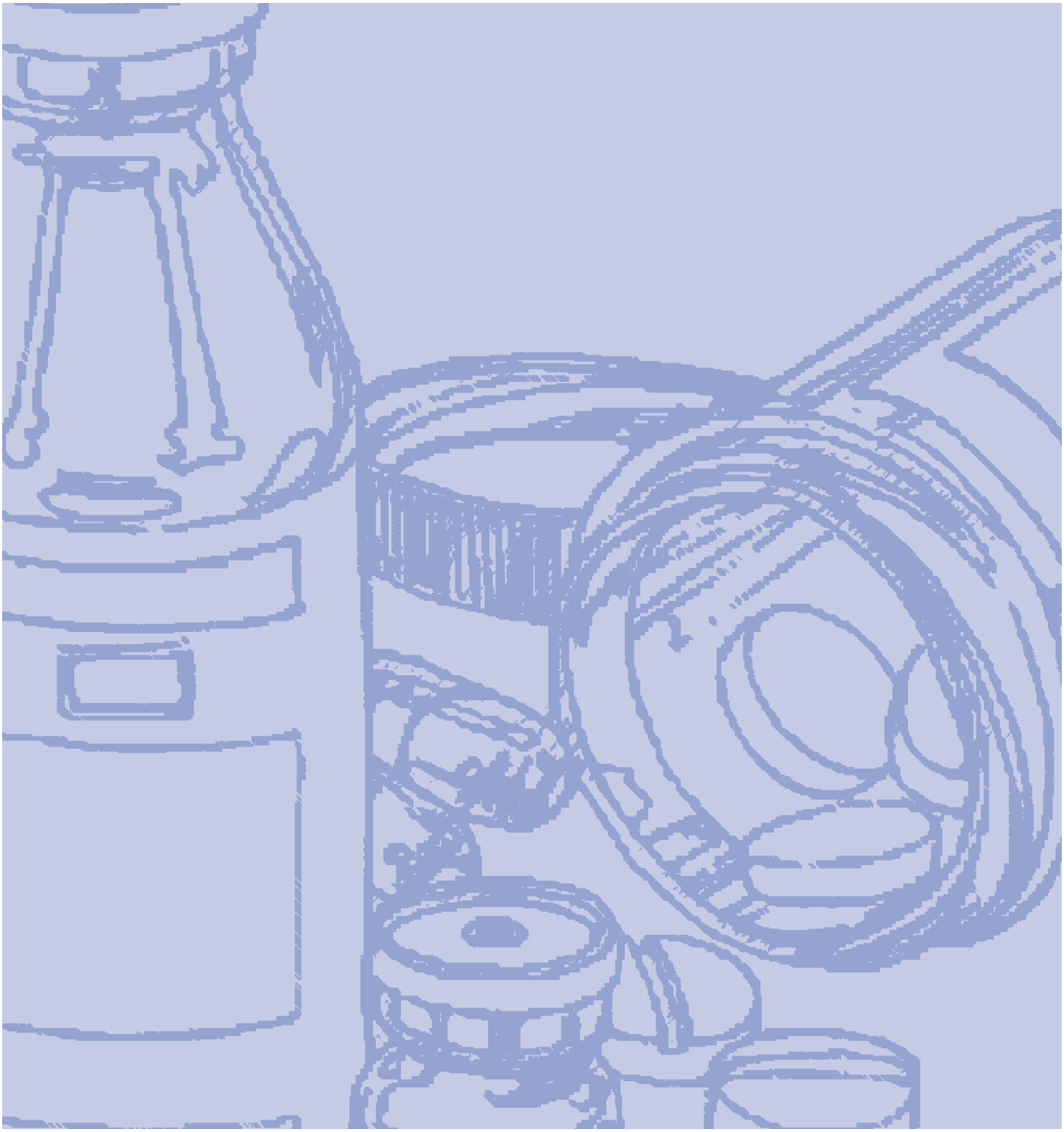
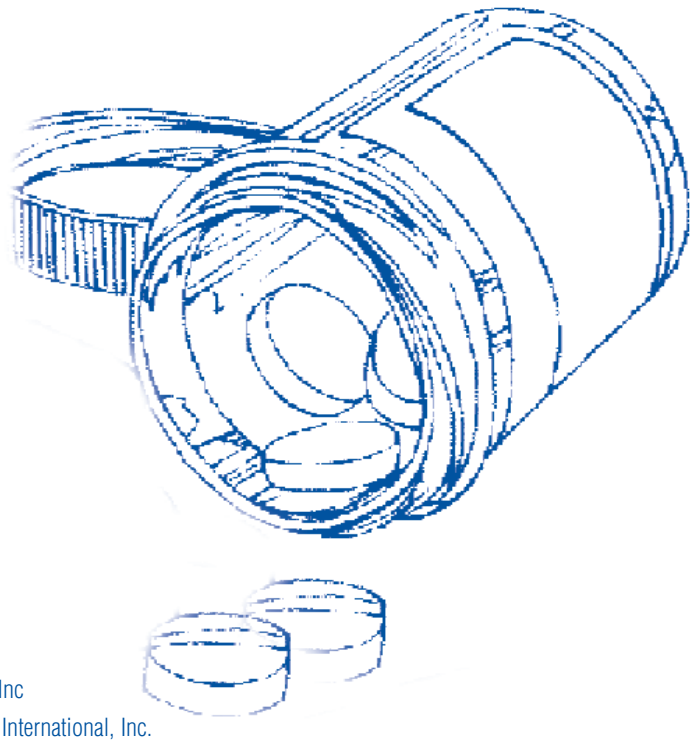


2003 FDA/Industry Statistics Workshop

Sponsored by the ASA Biopharmaceutical Section and the FDA Statistical Association

"STATISTICS: FROM THEORY TO REGULATORY ACCEPTANCE"

September 18–19, 2003
Hyatt Regency Bethesda — Bethesda, Maryland



2003 FDA/INDUSTRY WORKSHOP ORGANIZING COMMITTEE

Co-Chairs: Ed Nevius - FDA/CDER
Wasima Rida - Statistics Collaborative
Corsee Sanders - Genentech, Inc

Charles Anello - FDA/CDER
Alex Bajamonde - Genentech, Inc
Christopher Barker - MEDTAP International, Inc.
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Stella Machado - FDA/CDER
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Karen Kesler - Rho, Inc.
John Lawrence – FDA/CDER
Janet Wittes – Statistics Collaborative

2003 FDA/Industry Statistics Workshop

September 18-19 • Bethesda Hyatt • Bethesda, Maryland

"Statistics: From Theory to Regulatory Acceptance"

Sponsored by the Biopharmaceutical Section of the American Statistical Association in collaboration with the Food and Drug Administration Statistical Association, this workshop provides an opportunity to exchange views with a broad range of individuals from regulatory agencies, the pharmaceutical and biotech industry, academia, and others interested in drug, biologics, and medical device development.

LOCATION:

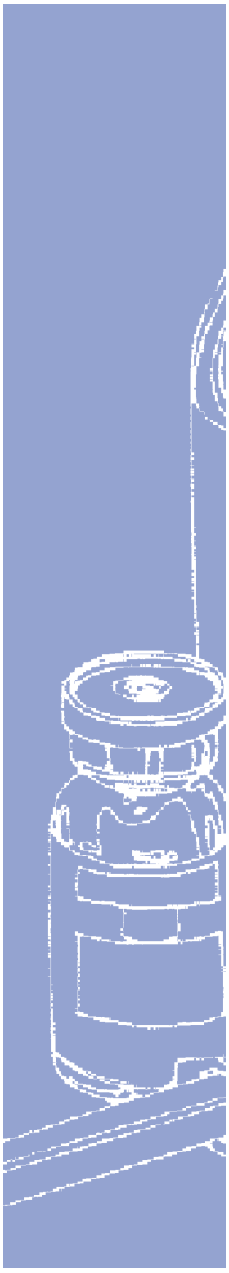
The workshop will be held at the Hyatt Regency Bethesda, conveniently located on the Metro red line just six miles from downtown Washington, DC.

REGISTRATION:

On-line registration at *http://www.amstat.org/meetings/fdaworkshop*. For further information, contact ASA Meetings Department, 1429 Duke Street, Alexandria, VA 22314, telephone (703) 684-1221 ext. 145, fax (703) 684-8069, email: *meetings@amstat.org*.

HOTEL RESERVATION:

Hotel rooms at the Hyatt Regency Bethesda are available at the single or double rate of $185 per night plus 12% lodging tax. Early arrivals or late departures can inquire about extension of the rate. The conference rate and availability cannot be guaranteed after August 22, 2003. Call toll free 1-800-633-7313 in the U.S. and Canada. Locally, call (301) 657-1234 or fax (301) 657-6453.



Wednesday September 17, 2003

1:00pm **Short Courses (Limited to 60 Participants per Course)**
A. **Handling Missing Data in Longitudinal Studies**—Ronald Helms (Rho, Inc.)
B. **Active Control Non-Inferiority Trials**—George Chi (FDA) and Gang Chen (Johnson & Johnson)

5:00pm Adjourn for the day

Thursday September 18, 2003

7:30am Continental Breakfast

8:30am Welcome—Corsee Sanders (Genentech), Wasima Rida (Statistics Collaborative), Ed Nevius (FDA)

8:45am **Plenary Session I: Flexible Designs**
Chairs: Ronald Helms (Rho, Inc.), Randy Davis (GlaxoSmithKline), and Sue-Jane Wang (FDA)

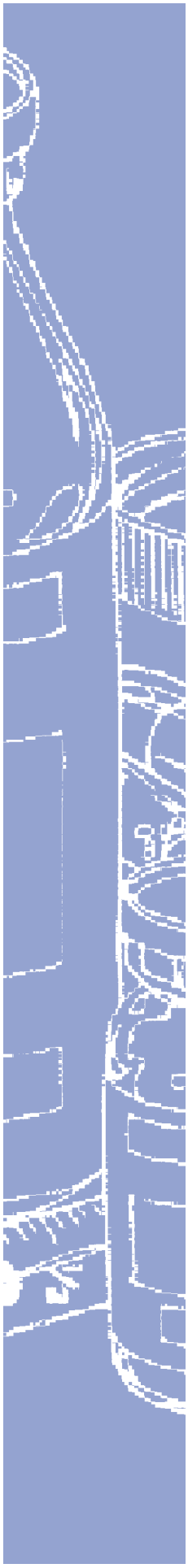
1. "Select the Winner in Drug Development"—Gordon Lan (Aventis Pharmaceuticals
2. "Use of Bayesian Modeling and Simulation for Design and Analysis of Clinical Trials"—Bill Gillespie (Pharsight)
3. "Adaptation of Clinical Trial Design and Inference"—James Hung (FDA)

10:15am Break

10:45am **Plenary Session II: Longitudinal Data Analysis—Issues and Recommendations**
Chairs: Devan Mehrotra (Merck) and Anna Nevius (FDA)

1. "Handling Incomplete Data in Clinical Studies"—Geert Molenberghs (Limburgs Universitair Centrum Belgium)
2. "Considerations Regarding Choice of the Primary Analysis in Longitudinal Trials with Dropouts: An FDA Perspective"—Bob O'Neill (FDA)
3. Discussant—Tom Louis (Johns Hopkins University)

12:15pm Lunch on your own



1:30pm **Plenary Session III: Trial Monitoring**
Chairs: Pilar Lim (Johnson & Johnson) and Greg Campbell (FDA)

1. "On the Superiority of Adaptive Designs"—Qing Liu (Johnson & Johnson) and Gordon Pledger (Johnson & Johnson)
2. "Changing Trial Design on the Fly"—Janet Wittes (Statistics Collaborative)
3. "Interim Analysis in Clinical Trials: A Bayesian Approach in the Regulatory Setting"—Telba Irony (FDA) and Gene Pennello (FDA)
4. Discussant—Keaven Anderson (Centocor)

3:00pm Break

3:30pm **Plenary Session IV: Perspectives on Safety Issues in Drug Development**
Chair: Cathy Melfi (Eli Lilly) and Aloka Chakravarty (FDA)

1. "Perspectives of Safety Issues in Drug Development-Industry Statistical Perspective" —Tim Costigan (Eli Lilly)
2. Academic Perspective—Carol Redmond (University of Pittsburgh)
3. FDA Perspective—George Rochester (FDA)

5:00pm Reception at Fellini's

Friday September 19, 2003

7:30am Continental Breakfast

8:30am **Parallel Sessions I**

A. Time to Event Data
Chairs: Davis Gates (Schering-Plough) and Gene Pennello (FDA)

1. "An Efficient Alternative to the Cox Model for Small Time-to-Event Trials"—Devan Mehrotra (Merck)
2. "Issues in the Analysis of Failure Time Data"—Rebecca Betensky (Harvard School of Public Health)
3. Panel Discussion—Tony Lachenbruch (FDA), James Hung (FDA), Devan Mehrotra (Merck), and Rebecca Betensky (Harvard School of Public Health)

B. Multinational Trials
Chairs: Janet Wittes (Statistics Collaborative) and John Lawrence (FDA)

1. "Delivering Robust Outcomes from Multinational Trials: Principles and Strategies" Andreas Sasheygi (Eli Lilly)
2. "Considerations for the Choice and Interpretation of Endpoints in International Trials of Antiretroviral Therapies"—Victor DeGruttola (Harvard School of Public Health)
3. "Multi-Clinic and Multi-National Trials: A Regulatory Perspective"—Charles Anello (FDA)

C. Genomics in Drug Discovery and Development
Chairs: Michelle Capozzolli (Framingham State) and Sue-Jane Wang (FDA)

1. "Complex Adaptive Systems and Human Health:Statistical Approaches in Pharmacogenomics"—Kim Zerba (Bristol-Myers-Squibb)
2. "Sample Size Selection for Gene Expression Studies"—Greg Warnes (Pfizer, Inc.)
3. "Cross-Study Validation of Molecular Classification in Cancer"—Giovanni Parmigiani (Johns Hopkins University)
4. "Selection of Differential Expression Genes in Microarray Experiment"—James Chen (FDA)

10:15am Break

10:30am **Parallel Sessions II**

A. Analysis Databases
Chairs: Ronald Helms (Rho, Inc.) and Steve Wilson (FDA)

1. Industry Perspective—Russ Helms (Rho, Inc.)
2. Academic Perspective—Dave Christiansen (Christiansen Consulting)
3. "A Regulartory Perspective"— Steve Wilson (FDA)

B. Post-Marketing Issues
Chairs: David Radley (Merck) and Charles Anello (FDA)

1. "Perspectives on Automated Methods for Pharmacovigilance Signal Detection" —Larry Gould (Merck)
2. "Rapid Cycle Analysis of Vaccine Safety"—Bob Davis (University of Washington)
3. FDA Perspective—David Graham (FDA)

C. Preclinical and Early Clinical Data
Chairs: Amrik Shah (Schering-Plough) and Karl Lin (FDA)

1. "Evaluation of Live Phase Results from Carcinogenicity Studies"—Wherly Hoffman (Eli Lilly)
2. "Peto Trend Test: Investigating the Impact of Tumor Misclassification""—Amrik Shah (Schering-Plough) and Melody Goodman (Harvard School of Public Health)
3. "Statistical Issues in Review of Carcinogenicity Studies Using Transgenic Mice"—Karl Lin (FDA) and Feng Zhou (FDA)

12:15pm Lunch on your own

1:30pm **Parallel Sessions III**

A. Randomization—Uses and Abuses
Chairs: Alex Bajamonde (Genentech) and Todd Sahlroot (FDA)

1. "Uses and Abuses of (Adaptive) Randomization: an Industry Perspective" —Benjamin Lyons (Johnson & Johnson) and Akiko Okamoto (Johnson & Johnson)
2. "Maximizing Power and Minimizing Treatment Failures Using Randomization" —William Rosenberger (University of Maryland at Baltimore County)
3. "Computer Intensive and Re-randomization Tests in Clinical Trials" —Tom Hammerstrom (FDA)

B. Diagnostic Evaluation
Chairs: Lee Kaiser (Genentech) and Lakshmi Vishnuvajjala (FDA)

1. "Methods Comparison Studies for Quantitative Nucleic Acid Assays" —Jacqueline Law (Roche Molecular Systems) and Art DeVault (Roche Molecular Systems)
2. "A Cautionary Note on the Robustness of Latent Class Models for Estimating Diagnostic Error without a Gold Standard"—Paul Albert (NCI) and Lori Dodd (NCI)
3. "Propensity Scores Methodology for Receiver Operating Characteristic (ROC) Analysis"—Marina Kondratovich (FDA)

C. Getting the Dose Right
Chairs: Gary Littman (Wyeth) and Stella Machado (FDA)

1. "Dose Spacing in Early Dose Response Clinical Trial Designs"- Naitee Ting (Pfizer)
2. "Adaptive Dose Selection: Getting the Most Out of What You Currently Know" —Andy Grieve (Pfizer and the University of Kent, UK)
3. "Risk and Benefit Assessments for Optimal Dose Selection Based on Exposure Response" —Peter Lee (FDA)

3:15pm Break

3:30pm **Special Interest Sessions**

A. Surrogate Endpoints in Vaccine Efficacy Trials
Chairs: Devan Mehrotra (Merck), Janet Wittes (Statistics Collaborative), and Sang Ahnn (FDA)

1. "Licensing a Vaccine on the Basis of Surrogate Endpoints: A Practical Example" —Robert Kohberger (Wyeth)
2. "On the Use of Surrogate Endpoints in HIV Vaccine Efficacy Trials" Steve Self (Fred Hutchinson Cancer Research Center)
3. FDA perspective

B. Statistical Methods in Advisory Panel Meetings
Chair: Mary Foulkes (FDA)

1. Joe Verter (Statistics Collaborative)
2. Greg Enas (Eli Lilly)

C. Statistical Issues in Medical Devices
Chair: Greg Campbell (FDA)

1. William C. Blackwelder (Biologics Consulting Group)
2. Frank Hurley (HD Consulting)
3. Lakshmi Vishnuvajjala (FDA)

5:00pm Adjourn

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