

FDA/Industry Workshop

The Information Revolution

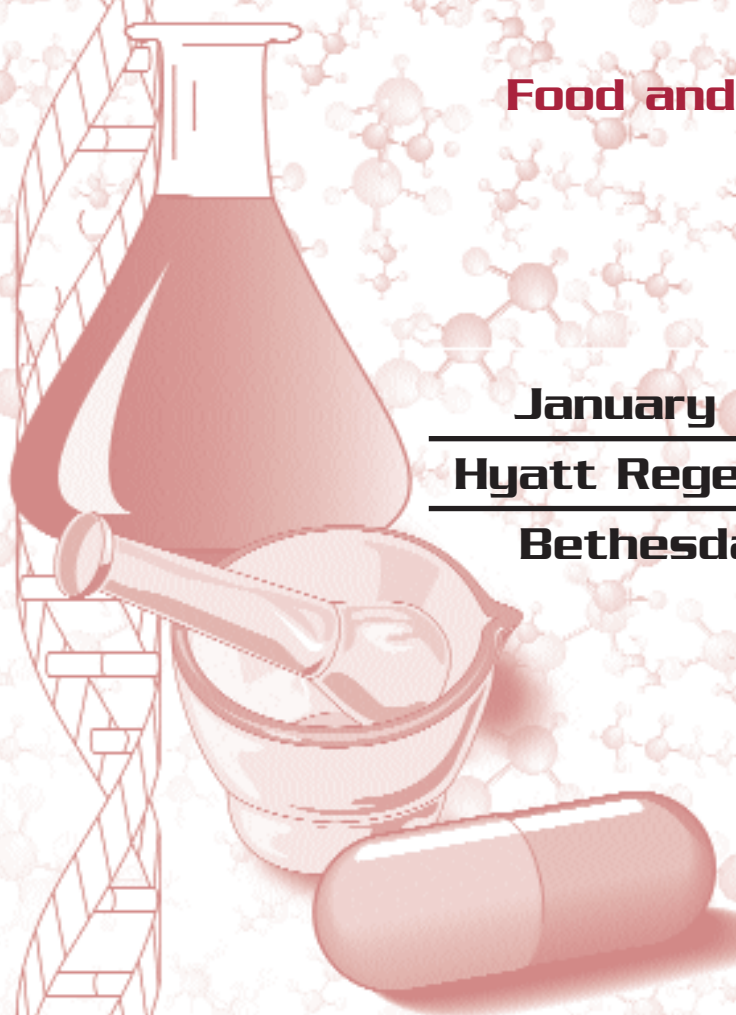
“Who’s Mining the Store?”

**Biopharmaceutical Section
American Statistical Association
and the
Food and Drug Administration**

January 17-18, 2002

Hyatt Regency Bethesda

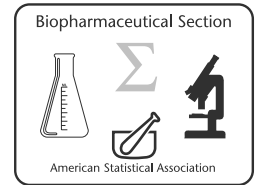
Bethesda, Maryland

An illustration in the bottom left corner shows a laboratory setup. It includes a large Erlenmeyer flask containing a dark liquid, a mortar and pestle with a white substance inside, and a single white capsule with a red band. The background of the entire page is a repeating pattern of molecular structures.

The workshop, sponsored by the Biopharmaceutical Section of the American Statistical Association and the Food and Drug Administration, brings together the members of the pharmaceutical industry and others interested in drug development and related topics to exchange views on issues that impact the analysis of data. Presenters include members of the FDA, industry, CRO's and academia. The two-day meeting offers a chance to exchange views informally with a broad range of statisticians from all of the represented areas.



Registration Form
American Statistical Association
Biopharmaceutical Section
and the Food and Drug Administration



FDA/Industry Statistical Workshop

The Informational Revolution — "Who's Mining the Store?"

January 17-18, 2002
Hyatt Regency Bethesda — Bethesda, Maryland

Forms Received Without Payment Will Be Returned

Instructions:

1. Print or type all information and retain a copy for your records.
2. Use a separate form for each registrant.
3. Purchase orders will not be accepted. No exceptions.
4. Mail form with payment to ASA Meetings Department, 1429 Duke St., Alexandria, VA 22314-3415. Fax form (credit card only) to (703) 684-8069.
5. Registration form must be received by December 18, 2001 to be processed at the reduced rate. Forms received after that date will be charged an additional \$25 late fee.
6. ASA Federal ID# 53-0204661.

REGISTRATION (Full registration includes conference materials, Thursday reception, continental breakfast and breaks)

Name: _____ ASA Member No. _____ (IF APPLICABLE)

Badge Information: _____
AFFILIATION CITY STATE/COUNTRY

Preferred Name for Badge: _____


Mailing Address _____

CITY STATE/PROVINCE ZIP/MAIL CODE COUNTRY

Daytime Phone (____) _____ Fax(____) _____

Email _____

- | | |
|--|---|
| Membership Type(s) | Employment Affiliation(s) |
| <input type="checkbox"/> BIOPHARM SECTION, ASA | <input type="checkbox"/> 1. University or College (non-student) |
| <input type="checkbox"/> ASA | <input type="checkbox"/> 2. Business Industry |
| <input type="checkbox"/> None | <input type="checkbox"/> 3. Government (Federal, state, local) |
| | <input type="checkbox"/> 4. Student |
| | <input type="checkbox"/> 5. Non-Profit Organization |
| | <input type="checkbox"/> 6. Other |

 This meeting is ADA accessible. Please check here if you need special services due to a disability and attach a statement regarding your disability needs.

REGISTRATION

Before December 18, 2001 (Advance)

- | | |
|-------|--|
| \$85 | Government or Student |
| \$175 | Biopharmaceutical Section or Academic (non-students) |
| \$215 | Others |

After December 18, 2001 (Late)

- | | |
|-------|---|
| \$110 | Government or Student |
| \$200 | Biopharmaceutical Section or Academic (non-student) |
| \$240 | Others |

AMOUNT ENCLOSED \$ _____
 (Complete payment section below)

Choose your session for Friday, January 17, 2001

Choose the order preference of the session you would like to attend (1-4).

- Parallel Sessions I**
- A _____
 - B _____
 - C _____
 - D _____
- Parallel Sessions II**
- A _____
 - B _____
 - C _____
 - D _____

Attending Reception-Thursday, January 17 yes no

PAYMENT

- Check made payable to American Statistical Association (in U.S. \$ on U.S. bank)
- Money Order (in U.S. \$ on U.S. bank)
- Visa MasterCard American Express
 (NO OTHER CARDS ACCEPTED)

 CARD NUMBER EXPIRATION DATE

 NAME AS IT APPEARS ON CARD

 CARDHOLDER'S SIGNATURE

REQUEST FOR REFUNDS RECEIVED AFTER JANUARY 7, 2002 WILL NOT BE HONORED

Annual FDA/Industry Statistics Workshop

January 17-18, 2002 • Bethesda Hyatt • Bethesda, MD

"The Information Revolution - Who's Mining the Store?"

Although the Workshop is sponsored by the Biopharmaceutical Section of the American Statistical Association and the Food & Drug Administration, we encourage attendance by our non-statistician colleagues in the medical, regulatory and data management areas.

Location: The Workshop will be held at the Hyatt Regency Bethesda, conveniently located on Metro Rail (Red Line) just six miles from the U.S. Capitol.

Hotel Reservations: Hotel rooms at the Hyatt Regency Bethesda are available at the single or double rate of \$170 plus tax. To make reservations, please call +1 301-657-1234 or 1-800-233-1234 and ask for the group rate for the "FDA Workshop". These rates are available until December 17, 2001. There are a limited number of hotel rooms available at the group rate. Make your reservations early.

For information contact ASA Meetings Department, 1429 Duke Street, Alexandria, VA 22314, phone +1 703-684-1221 ext. 148, fax +1 703-684-8069, email: meetings@amstat.org.

Thursday, January 17, 2002

8:00am	Continental Breakfast
8:30am	Welcome — Greg Enas (Eli Lilly), Anna Nevius (FDA)
8:45am	Plenary Session I
	"Strategic Planning for Substantial Evidence"
	Chairs: Ronald W. Helms (Rho), Aloka Chakravarty (FDA)
	1. "Design Strategies for Phase II through III: The Traditional Approach Compared to New Strategies Using Fewer, Larger Studies With Multiple Intermediate Analyses" - Ronald W. Helms (Rho), Katherine L. Monti (Rho), Dennis D. Wallace (Rho), Karen L. Kesler (Rho)
	2. "Meta-Analysis in Global Regulatory Submissions" - Phil Poole (Pfizer)
	3. "Strategic Planning Issues: A FDA Reviewer's Perspective" – Stan Lin, (FDA)
10:15am	Break
10:45am	Plenary Session II
	"e-Predictions, e-Design, e-Analysis"
	Chairs: David Stock (BMS), Stella Machado (FDA), Steve Wilson (FDA)
	1. "Predicting Human Safety Data: Screening and Computational Approaches" - Grushenka H.I. Wolfgang (ddplatform), Dale E. Johnson (ddplatform)
	2. "Application of Computer Assisted Trial Design (CATD) to Better Design and Interpret Clinical Trials" Dan Weiner (Pharsight)
12:15pm	Lunch on your own
1:30pm	Plenary Session III
	"Causal Inference: Anything but Casual"
	Chairs: Cathy Melfi (Eli Lilly), Gene Pennello (FDA)
	1. "Missing Data Sensitivity Analysis: A Case Study" - Kinley Larntz (University of Minnesota)
	2. "Inference From Multiple Studies" - Chuck Anello (FDA)
	3. "Getting More Information From Complex Randomized Experiments" - Donald Rubin (Harvard)
3:00pm	Break
3:30pm	Plenary Session IV
	"Experimental Studies: Ethical Norms and Fraud"
	Chairs: Ram Suresh (Schering-Plough), Peter A. Lachenbruch (FDA),
	Panel Discussion: Susan Ellenberg (FDA), Samuel Heft (Schering-Plough), Peter A.Lachenbruch (FDA), Victor DeGruttola (Harvard)
5:00pm	Reception at Fellini's
6:00pm	Dinner on your own

Friday, January 18, 2002

8:00am	Continental Breakfast
8:30am	Parallel Sessions I
	<i>Pick one of the following sessions. These sessions allow for small group discussion following the speakers presentations. A break is included around 2:00pm</i>
	<i>These sessions include a break for 20 minutes around 9:45AM</i>
	A. Safety Evaluation
	Chairs: Greg Wei (Pfizer), Yi Tsong (FDA)
	1. "The Role of Statistics in Nonclinical Safety Evaluation" – Wherly Hoffman (Eli Lilly)
	2. "Statistical Methods and Interpretation of Data in Special Populations" – Timothy H Montague (GlaxoSmithKline)
	3. "Model-Based Correction to QT Interval for Heart Rate for Assessing Mean QT Interval Change Due to Drug Effect" – Greg Wei (Pfizer)
	4. "Statistical Issues in Safety Evaluation" – George Rochester (FDA)
	5. "The Role of FDA Postmarketing Drug Safety Surveillance on Liver Events" – Min Chen (FDA)

B. Choice of Control Group For Non-Inferiority Trials

Chairs: Devan Mehrotra (Merck), Chuck Anello (FDA),

1. "Choosing the Non-Inferiority Margin – Delta: How Creative Can It Be" - Irving Hwang (Harvard)
2. "Noninferiority is Not Enough" - Janet Wittes (Statistics Collaborative)
3. "Clinical Trial Control Groups: The Great Debate on Ethics" - Susan Ellenberg (FDA)

Discussant: Steve Snapinn (Merck)

C. Issues in the Design and Analysis of Diagnostic Clinical Trials

Chairs: John Castellana (Berlex), Mike Welch (FDA)

Session I

1. "Designing Clinical Trials with Diagnostic Endpoints"- Mike Welch (FDA)
2. "Challenges When Assessing Efficacy Using Multiple Blinded Readers" – Rocco Ballerini (Nycomed Amersham)
3. "ROC Thinking in the Clinical Development of Diagnostic Agents" – Jim Goin (DataMedix)

Session II

1. "Statistical Issues in Diagnostic Imaging - A CBER Perspective"– Satish Misra (FDA), Peter A. Lachenbruch (FDA)
2. "Evaluation of Diagnostic Accuracies of Medical Tests with Partial Verification" Xiao-Hua (Andrew) Zhou (Indiana University)
3. "Nonparametric Methods for Analyzing Diagnostic Test Performance" – Joerg Kaufmann (Schering AG)

D. Current State of the Art in HRQoL Measurement and Future Directions

Chairs: Chris Barker (Roche), Lisa Kammerman (FDA), Clare Gnecco (FDA)

1. "Prospects and Problems in the Use of IRT in Health Outcomes Assessment", Colleen McHorey (Indiana University)
2. "Evidence Supporting Psychometric Characteristics of Health-Related QoL Instruments for Labeling and Promotional Claims", Dennis Revicki (MEDTAP), Nancy Klein Leidy (MEDTAP)
3. "Interpretation of QoL Outcomes: Issues that Affect Magnitude and Meaning", Ralph Turner

Discussants: Robert Meyer (FDA), Nancy Santanello (Merck), Dennis Revicki (MEDTAP), Nancy Klein Leidy (MEDTAP), Zafar Hakim (Roche), Marcia Testa (Phase V)

11:15am Lunch on your own

12:30pm **Parallel Sessions II**

Pick one of the following sessions. These sessions allow for small group discussion following the speakers presentations. A break is included around 2:00pm

A. Genomic Statistics in the Regulated Medical Products Industry

Chairs: Randy Davis (GlaxoSmithKline), Greg Campbell (FDA), Sue-Jane Wang (FDA)

1. "Statistics, Genomics and Genetic Tests: An FDA Perspective" - Greg Campbell (FDA)
2. "Current Status of Therapeutic Drug Discovery Using Genetic Information" - Sue-Jane Wang (FDA)
3. "Interactive Analysis of Genetic Data of Clinical Trials" – Stan Young (GlaxoSmithKline)
4. "National Center for Toxicological Research: Statistical Issues in Normalizing cDNA Array Data" Robert Delongchamp (NCTR), Cruz Velasco (NCTR)
5. "Statistical Issues in Analyzing Protein Chip Data" - Lu-Ping Zhao (Fred Hutchinson Cancer Research Center)

B. Informatively Censored Longitudinal Studies

Chairs: Gary Littman (Wyeth), Janice Derr (FDA)

1. "An Overview of Current Methods of Dealing with Clinical Data with Informative Censoring" – Richard Entsuah (Wyeth-Ayerst)
2. "Analysis of Longitudinal Data with Random Effects and Informative Censoring" - Margaret Wu (NHLBI)

C. Flexible Designs

Chairs: Corsee Sanders (Genentech), Kooros Mahjoob (FDA)

1. "Strategies of Adaptive Clinical Trial with the Option to Drop One of the Two Active Treatments at Interim Look" – Yi Tsong (FDA)
2. "Examples of Mid-Study Design Adjustments" - Mark Ashby, Ph.D. (Genentech)
3. "Problems and Issues in Implementing Trial Designs" - Gordon Lan (Pfizer)
4. "Phase 2/3 Combination Clinical Trials to Accelerate Drug Development" – Qing Liu (Cephalon)

D. Global Bridging Strategies

Chairs: Kim Perry (Pharmacia), James Hung (FDA)

1. "Experiences with Bridging Data From a Single Japanese Study to a Large Western Database" - Scott Haughie (Pfizer)
2. "On Sample Size Determination in Evaluation of Bridging Evidence for Pharmaceutical Products" Dr. Jen-Pei Liu (National Health Research Institutes)
3. "Bridging Strategies for Global Integration of Clinical Studies and Registration" - Tamie K. Bergstrom, Ph.D. (Pharmacia)
4. "Geotherapeutics: A Science Based Approach to Global Bridging Programs" - Ted Grasela, PharmD, Ph.D. (Cognigen)

Discussant: H.M. James Hung (FDA)

3:15pm **Special Interest Parallel Sessions**

1. "Statistical Issues with Medical Devices" - Greg Campbell (FDA)
2. "Analysis of Mixed Models" - Ron Helms (Rho)

5:00pm **Adjourn**