ANNOUNCEMENT

International Chinese Statistical Association

(ICSA)

Short Courses in Pharmaceutical/Industrial Statistics/Programming

To be presented at

ICSA 2000 Applied Statistics Symposium

June 1, 2000

Embassy Suites Hotel, Piscataway, NJ

- For extra information about the short course please contact: Frank Shen, Bristol-Myers Squibb Co., (609) 818-6505, shenc@bms.com, or visit ICSA web site: *http://www.icsa.org*
- For registration please use the Symposium registration form and make your check payable to "ICSA 2000 Applied Statistics Symposium".
- Registration to the Symposium program on 6/2-3 is highly encouraged but not required for short course participants. A preliminary program and registration form are attached for your information.

Course 001: Individual and Population Bioequivalence
(1:00 PM - 4:00 PM)

Instructors: *Walter Hauck*, Ph.D. and *Terry Hyslop*, M.S., the Biostatistics Section, Division of Clinical Pharmacology, Thomas Jefferson University, Philadelphia PA.

Course Outline:

What and why

- The concepts of individual and population bioequivalence
- Contrast to current practice of average bioequivalence

Criteria

- Brief summary of work in this area
- Description of critera chosen by the FDA

FDA guidances

- Summary of draft and final guidances that recommend population and/or individual approaches

Implementing individual and population bioequivalence

- Testing individual and population BE criteria
- Sample size requirements

About the Instructors: Walter Hauck is Professor and Head of the Biostatistics Section, Division of Clinical Pharmacology, Thomas Jefferson University, Philadelphia PA. He received his B.S. in Mathematics and Economics from Carnegie-Mellon University in 1969 and his M.S. and Ph.D. in Statistics from Harvard University in 1970 and 1975, respectively. Prior to Thomas Jefferson, he worked at the Harvard Medical School, Worcester Polytechnic Institute, Illinois Cancer Council, Northwestern University Cancer Center, and the University of California at San Francisco. He is the author or co-author of over 140 peer-reviewed papers and has served as statistical consultant to working groups within FDA's Office of Pharmaceutical Sciences. Current research interests include statistical methods for equivalence trials, generally, and bioequivalence trials, in particular, application of equivalence approaches in other contexts, and clinical pharmacology statistics.

Terry Hyslop is Principal Biostatistician and Director, Biostatistics Consulting Unit in the Biostatistics Section, Division of Clinical Pharmacology, Thomas Jefferson University in Philadelphia, PA. Terry is co-author with Francis Hsuan and Daniel Holder of "A small sample confidence interval approach to Individual Bioequivalence", Statistics in Medicine, in press. Their methods have been recommended for both IBE and PBE in the FDA statistics guidance.

Maximum Class Size: ***50***. Enrollment will be based on first come first serve. Early registration is encouraged.
Fee: Prior to 4/30/00 Regular $90 Student $45; After 4/30/00 Regular $100 Student $50.

Course 002: ICH E10 Guideline and Design Issues in Non-inferiority/ Equivalence Trials

(9:00 AM - 4:00 PM)

Instructor: *Irving K. Hwang*, Ph.D., Irving Consulting Group, Pluckemin, New Jersey

Course Outline: The double-blind placebo-controlled trials have been the gold standard in clinical development for many decades. It continues to provide a useful means to demonstrate the efficacy of a new test drug in a confirmatory way by showing its superiority to placebo. With the existence of drugs of proven efficacy, the conduct of clinical trials with placebo as the control sometimes posed ethical dilemma. As more and more effective drugs become available and less and less breakthrough new drugs emerge, the objective of clinical investigation amends. Oftentimes, It seeks non-inferiority/equivalence of the new drug to an existing effective standard drug in active controlled trials.

This short course first provides an update on the development of the ICH E10 guideline: Choice of Control Group in Clinical Trials and reviews the crucial issues the E10 guideline intends to convey. Then, it discusses the design issues in non-inferiority/equivalence trials that include the choice of the non-inferiority/equivalence margin, the forms of the null and alternative hypotheses and confidence intervals, as well as sample size and power calculations. Finally, it addresses the inherent difficulties and some useful design alternatives to the non-inferiority/equivalence trials.

The focus of this course will be primarily on statistical concept, reasoning, and practices. General issues on clinical trial design with special emphasis on non-inferiority/equivalence trials will be discussed. Examples for trials in selected therapeutic areas will be given for illustration and exercise purposes. Appreciation and understanding of these issues ensure that when a clinical trial with a properly selected control group is designed and conducted, it reaches its intended objective(s) with scientific credibility and regulatory approvability. New issues emerged at the recent ICH Steering Committee and E10 Expert Working Group (EWG) meetings in Japan will also be reviewed.

About the Instructor: Dr. Irving Hwang is currently President, Irving Consulting Group; Visiting Professor, Rutgers University; PhRMA Deputy Topic Leader, ICH E-l0 EWG; and Pharmaceutical Scientific Advisor, Bureau of Pharmaceutical Affairs, Rep. of China. Dr. Hwang has gained over two decades of global drug development experience with major pharmaceutical companies in design and analysis of clinical trials for development of new drugs and vaccines. Dr. Hwang was Vice President & Head, Global Biometrics, Hoechst Marion Roussel, Inc. (HMR); Sr. Director, Clinical Research Operations, Hoechst Roussel Pharmaceuticals, Inc. (HRPI); and Sr. Director, Clinical Biostatistics & Research Data Systems, Merck. He was Member, PhRMA BSS Steering Committee and Co-Chair, PMA/FDA Workshop on Clinical Trials Monitoring and Interim Analysis.

Dr. Hwang received his Ph.D. in Statistics from the Wharton School, University of Pennsylvania. His research interests include PK/PD modeling, regression analysis, robust methods, survival analysis, longitudinal analysis, interim analysis/group sequential methods, and confirmatory clinical trial methodology including design and analysis of landmark megatrials and non-inferiority/equivalence trials.

Maximum Class Size: ***50***. Enrollment will be based on first come first serve. Early registration is encouraged.

Fee: Prior to 4/30/00 Regular $180 Student $90; After 4/30/00 Regular $200 Student $100. Lunch is included.

Course 003: Experiments: Planning, Analysis, and Parameter Design Optimization

(9:00 AM - 4:00 PM)

Instructor: *C. F. Jeff Wu*, Ph.D., University of Michigan

Course Outline: This one-day course will be based on the book by Jeff Wu and Mike Hamada which will be published by John Wiley in March of 2000. The short course notes will be made available to the participants. This book contains many new methods not found in existing textbooks, and covers more than 80 data sets and 200 exercises. The new tools covered include robust parameter design, use of minimum aberration criterion for optimal factor assignment, orthogonal arrays of economic run size, analysis strategies to exploit interactions, experiments for reliability improvement, and analysis of experiments with non-normal responses. The course will cover basic tools and illustrate them with data from real experiments. The course will be divided into four units:

- Basic principles for design of experiments including two-level full and fractional factorial designs and basic analysis tools. Techniques for resolving ambiguities in aliased effects and the minimum aberration criterion for optimal factor assignment.
- Choice of optimal blocking schemes for two-level designs. Three-level fractional factorial designs of 27 and 81 runs. Mixed 2- and 4-level designs. A guide to the use of design tables.
- Nonregular designs including Plackett-Burman designs and mixed-level orthogonal arrays. Their basic statistical properties and practical use. Use of design tables. Analysis of experiments based on nonregular designs, including the exploitation of interactions
- Robust parameter design for variation reduction. Layout techniques: cross arrays and single arrays. Modeling strategies. Choice of cross and single arrays and use of design tables. Review on signal-to-noise ratio.

The course is targeting industrial or academic statisticians who are interested in learning modern and effective tools in the design and analysis of experiments. Some basic knowledge on regression analysis and analysis of variance are assumed. No prior background in experimental design is required.

About the Instructor: C. F. Jeff Wu is H. C. Carver Professor of Statistics and also Professor of Industrial and Operations Engineering at the University of Michigan, Ann Arbor. He was formerly the GM/NSERC Chair in Quality and Productivity at the University of Waterloo, which was jointly funded by General Motors of Canada and the Natural Sciences and Engineering Research Council of Canada.

He taught at the Statistics Department at the University of Wisconsin from 1977-1988 prior to join U. of Waterloo. He is a Fellow of the IMS and the ASA. He received many prestigious awards including COPSS Award in 1987, Wilcoxon Prize in 1990, Brumbaugh Award in 1992, and Jack Youden Prize in 1997. He gave the 1998 P. C. Mahalanobis Memorial Lecturer at the Indian Statistical Institutes.

He received his BS in Mathematics from National Taiwan University in 1971 and Ph.D. in Statistics from the University of California, Berkeley in 1976. His research interests include experimental design, quality and reliability improvement, biotech and preclinical applications, robust product/process design, modeling of complex systems, survey sampling and computer-intensive statistical methods. He is the author or co-author of over 100 research papers and a recent book entitled "Experiments: Planning, Analysis, and Parameter Design Optimization"(Wiley, 2000).

Maximum Class Size: ***50***. Enrollment will be based on first come first serve. Early registration is encouraged.

Fee: Prior to 4/30/00 Regular $180 Student $90; After 4/30/00 Regular $200 Student $100; please make a note in your registration if you would like to purchase the textbook ($89.95) at door. Lunch is included.

Course 004: The First Course in Oracle Client/Server Concepts

(9:00 AM - 4:00 PM)

(The Best and Cheapest Oracle Course in Town!)

Instructor: *Andy Lachapelle*, Sideris Consulting Group.

Outline: The many varied software products and tools from Oracle can be overwhelming to new users as can be the concept of client/server technology itself. Objective and unbiased discussions show how the entire set of Oracle products may be integrated to develop sophisticated client/server applications.

- Client/Server Architecture
- Relational Database Management Systems
- Personal Oracle
- Workgroup Server/2000
- The Oracle Server
- Server Configurations
- SQL & SQL*PLUS Concepts
- SQL*PLUS Functions
- What is PL/SQL?
- Client/Server Programming
- Major Development Tools
- Internet Products

About the Instructor: Mr. Lachapelle has over 20 years industry experience and joined the Sideris Consulting Group in 1997 from ESPN Corporation. He is one of the most requested Oracle technology instructors in the company. Mr. Lachapelle's extensive background also includes several years' service at the Hartford Insurance Group and Computer Processing Institute. As an instructor/consultant with SIDERIS, Mr. Lachapelle is proficient in developing and teaching the following topics: Oracle Developer, Oracle Designer, and Oracle Discoverer technologies. Mr. Lachapelle is one of the most valuable Oracle experts and has held key Oracle consulting positions for several years.

Maximum Class Size: ***35***. Enrollment will be based on first come first serve. Early registration is encouraged.

Fee: Prior to 4/30/00 Regular $180 Student $90; After 4/30/00 Regular $200 Student $100. Lunch is included.

Course 005: Statistical Designs for Genetic Epidemiology
(9:00 AM - 4:00 PM)

Instructor: Terri H. Beaty, Ph.D. Department of Epidemiology, and Kung-Yee Liang, Ph.D., Department of Biostatistics, Johns Hopkins University.

Outline: It has become increasingly clear in the past decade or so that genetic factors play crucial etiological roles for many common diseases including cancer, coronary heart disease, allergy and psychiatric disorders. Genetic epidemiology is a relatively new field which utilizes conventional epidemiologic designs and methods to explore the role genetic factors play in determining disease, with the ultimate goal of identifying gene(s) controlling risk to complex disease. The followings represent some key questions to be answered in genetic epidemiologic studies:

- Do disease cluster in families?
- What are the causes of familial aggregations?
- How is genetic susceptibility inherited?
- Is the genetic model useful for predicting risk?
- How to locate susceptibility genes?

In this short course, we discuss, from design viewpoints, approaches to address some of the questions listed above. We will first focus on case control association studies. These include as a special case the family case-control design to measure familial aggregation, case-control design with unrelated (or related) controls to detect gene-environment interaction and the case-parent trio design to test for linkage disequilibrium. The second part is devoted to designs that are useful to localize disease gene(s). These include as a special case the multiplex family design and affected relative pairs design. For each design/question considered, we discuss statistical methods that have been developed, their pros and cons along with their applications to some real studies.

About the Instructors: Dr. Terri Beaty received her Ph.D. in Human Genetics from University of Michigan in 1978 and is currently Professor and Director of Genetic Epidemiology Program, Department of Epidemiology, Johns Hopkins University. Dr. Beaty is the co-author of the book entitled "Fundamentals of Genetic Epidemiology" in 1993 by Oxford University Press. Dr. Kung-Yee Liang received his Ph.D. in Biostatistics from University of Washington in 1982 and is currently Professor at the Department of Biostatistics, Johns Hopkins University. Dr. Liang is an ASA fellow and a co-author (with Peter Diggle and Scott Zeger) of the book *Analysis of Longitudinal Data* published in 1994.

Drs. Beaty and Liang are co-Acting Directors for the Quantitative Genetic Program in Public Health at the Johns Hopkins School of Hygiene & Public Health.

Maximum Class Size: ***50***. Enrollment will be based on first come first serve. Early registration is encouraged.

Fee: Prior to 4/30/00 Regular $180 Student $90; After 4/30/00 Regular $200 Student $100. Lunch is included.

Course 006: Presentation Skills – How to make a Good Statistical Presentation
(7:00 PM - 9:30 PM)

Instructor: Weichung Joe Shih, Ph.D., University of Medicine and Dentistry of New Jersey.

Outline: Effective presentation does not come out naturally for many of us. It requires observation, training, and practice. This is especially true for presenting statistical work in English while English is not the mother language for most ICSA members. In this 2&1/2-hour evening workshop we will discuss principles and tips of making an effective statistical presentation in various occasions including, for example, interview seminars (academia versus industry), professional society meetings (contributed versus invited paper sessions), or informal talks in a small group setting. This workshop is to help those who are about graduating from school or have just started the professional career. The course material will be the instructor's personal collection of examples from many years' experience in observing and practicing statistical presentations. Registered students are encouraged/expected to bring their own presentations to the workshop for practice and group discussion.

About the Instructor: Dr. Shih is Professor and Director, Biometrics Division, School of Public Health and Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey. Prior to joining UMDNJ, he was Director, Scientific Staff at Biostatistics and Research Information Management, Merck Research Laboratories. For more than 18 years he has made significant contributions to numerous clinical development programs. He has also provided leadership in biostatistics research in drug development, especially in sample size re-estimation for ongoing clinical trials. He is an ASA fellow and associate editor for two refereed journals. He received his Ph.D. from University of Minnesota in 1981.

Maximum Class Size: ***15***. Enrollment will be based on first come first serve. Early registration is encouraged.
Fee: Prior to 4/30/00 $35; After 4/30/00 $40

INTERNATIONAL CHINESE STATISTICAL ASSOCIATION *(ICSA)*

2000 Applied Statistics Symposium Preliminary Program

June 1 - 3, 2000

Embassy Suites, 121 Centennial Avenue, Piscataway, New Jersey, USA

THURSDAY, JUNE 1, 2000

9:00 a.m. - 9:30 p.m. SHORT COURSES & WORKSHOP

FRIDAY, JUNE 2, 2000

Topics of Invited Sessions:

- **Missing Covariates**
- **Pre-Clinical and Statistical Design Issues at the FDA**
- **SAS Programming**
- **Statistical Applications in Finance**
- **Quality of Life**
- **Biased Sampling**
- **Testing and Diagnostic Issues at the FDA**
- **Electronic Submission of NDA (eSub)**
- **Business Statistics**
- **Statistics in Taiwan**
- **Recent Development in Semiparametric Likelihood Inference**
- **Statistical and Regulatory Issues in Active Control Trials**
- **Career Mentoring and Development**
- **Data-Analytic Techniques in Biostatistical Modeling**

6:00 p.m. DINNER RECEPTION Sunny Palace Restaurant

Invited Dinner Speaker

Dr. Henry Lee, Commissioner of Public Safety, State of Connecticut

SATURDAY, JUNE 3, 2000

Special Invited Session - Keynote Speaker

Statisticians, Statistical Science and the Future.

Prof. Marvin Zelen, School of Public Health, Harvard University

Topics of Invited Sessions:

- **Statistical Genetics**
- **Adaptive Design and Analysis of Clinical Trials**
- **CRO -Culture and Development**
- **Challenges and Opportunities in Drug Discovery Research**
- **Data Mining Applications in Industry**
- **NIH Session**
- **Industrial Statistics**
- **Biostatistics in Cancer Studies**

REGISTRATION FORM

(Registration Is Required for All Participants and Speakers)

ICSA 2000 APPLIED STATISTICS SYMPOSIUM

June 1–3, 2000

Embassy Suites, Piscataway, New Jersey, USA

Name (English): _____ (Chinese): _____
(Last) (First) (Middle)

Affiliation: _____

Mailing Address: _____

Phone: _____ **Fax:** _____ **E-Mail:** _____

Short Course/Special Workshop and Symposium Registration

Short Course/Special Workshop (Thursday, June 1): $_____

Course Title	Time	Check (√)
1. Individual and Population Bioequivalence	9:00 a.m.- 12:00 noon	
2. ICH E-10 Guidelines & Design Issues in Non-Inferiority/Equivalence Trials	9:00 a.m.- 4:00 p.m.	
3. Experiments: Planning, Analysis and Parameter Design Optimization	9:00 a.m.- 4:00 p.m.	
4. The First Course in Oracle Client/Server	9:00 a.m.- 4:00 p.m.	
5. Statistical Designs for Genetic Epidemiology	9:00 a.m.- 4:00 p.m.	
6. (Special Workshop) Presentation Skills – How to Make a Good Statistical Presentation	7:00 p.m.- 9:00 p.m.	

Course/Workshop	By April 30	After April 30	Check (√)
Short Course (1 day)			
Regular	$180	$200	
Student	$90	$100	
Short Course (1/2 day)			
Regular	$90	$100	
Student	$45	$50	
Special Workshop	$35	$40	

(Short course registration fee includes lunch on June 1.)

Symposium (Friday & Saturday, June 2 -3) : $_____

Membership Type	By April 30	After April 30	Check (√)
Regular Member	$75	$85	
Regular Nonmember	$115	$125	
Student Member	$20	$25	
Student Nonmember	$40	$45	

(Symposium registration fee includes lunches and coffee breaks on June 2-3.)

ICSA Membership for 2001	____Annual Regular Membership ($40)	$_____
	____Annual Student Membership ($20)	$_____
	____Lifetime Permanent Membership ($400)	$_____
Note: New member needs to fill out ICSA Membership Application Form (which can be downloaded from http://www.icsa.org).		
Banquet (Friday, June 2):	$35 + ____ × $25 for each additional guest	$_____
Donation:		$_____
Total Amount Included:		$_____

Please Send Registration Form with Check *(Payable to ICSA)* to Symposium Registrar:

Mr. Jun Zhao, ICSA Symposium Registrar
Department of Statistics
Hill Center, Busch Campus
Rutgers, The State University of New Jersey
110 Frelinghuysen Road
Piscataway, NJ 08854-8019
Phone: (732) 445-2641; Fax: (732) 445-3428; E-Mail: JJZhao@Stat.Rutgers.edu

CANCELLATION POLICY: *Cancellation made by **May 15, 2000** will have 80% fee refunded. No refund will be honored for cancellation made after this date.*

HOTEL INFORMATION

Participants should book their own hotel reservations. ICSA has arranged special group rates (for June 1-3, 2000 only) with the following two hotels:

1. **Embassy Suites** (Phone: 732-980-0500 or 1-800-EMBASSY; Fax: 732-457-9610)
   121 Centennial Avenue, Piscataway, New Jersey, 08854
   $102/day + tax.

2. **Holiday Inn Somerset** (Phone: 732-356-1700 or 1-800-465-4329; Fax: 732-356-0939)
   195 Davidson Avenue, Somerset, New Jersey, 08873
   $69/day + tax (single or double room) – Reservation received after **May 12, 2000** will be subject to availability and may not qualify for special group rate.

Directions to the meeting site (Embassy Suites):

From the New Jersey Turnpike:
Take Exit 10, follow signs for 287 North, follow 287 North for approximately 11 miles to Exit 9. At end of exit ramp turn left onto River Road, take the next right-hand *jughandle* turn for Centennial Avenue. At next light, turn left into the hotel.

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From the Garden State Parkway Northbound:
Take Exit 127, follow signs for 287 North, follow 287 North for approximately 11 miles to Exit 9. At end of exit ramp, turn left onto River Road, take the next right-hand *jughandle* turn for Centennial Centennial Avenue. At next light, turn left into the hotel.

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From the Garden State Parkway Southbound:
Take Exit 129, follow signs for 287 North, follow 287 North for approximately 11 miles to Exit 9. At end of exit ramp, turn left onto River Road, take the next right-hand *jughandle* turn for Centennial Avenue. At next light, turn left into the hotel.

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From Route 78:
Take the Route 287 South Exit, follow 287 South to Exit 9. At end of end of exit ramp turn right onto River Road, take the next right-hand *jughandle* turn for Centennial Avenue. At the next light, turn left into the hotel.