PROGRAMME OF THE FIFTY-SEVENTH ANNUAL DEMING CONFERENCE ON APPLIED STATISTICS

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December 10 – December 12, 2001: Three-Day Conference
Resorts Casino Hotel, Atlantic City, NJ

Short Courses: – December 13, 2001
1. Measurement Error in Nonlinear Models
2. Experimental Design and the Statistical Analysis of Spotted Microarrays
Short Course: - December 14, 2001
3. Challenges Posed by the Human Genome Project

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Walter R. Young, Chair
Wyeth-Ayerst Research
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Conference Chairman
Walter R. Young*
Wyeth-Ayerst Research
P.O. Box 42528
Philadelphia, PA 19101
(484) 865-5640
Fax No.: (484) 865-0104
youngw@war.wyeth.com

Registrar
William I. Martin
Customized Management Systems, Ltd.
18-65 211 St., Suite 2F
Bayside, NY 11360-1814
(718) 631-2375
Fax No.: (718) 631-2375
wim-cms@att.net

Transactions
Edward Warner
Schering-Plough Corporation
Mail Stop U-1-1 1600
1011 Morris Ave.
Union, NJ 07083
(908) 820-6988
Fax No: (908)-820-6003
ed.warner@spcorp.com

Arrangements
Satish Laroia
Larson Associates
33 Aspen Circle
Edison, NJ 08820
(973) 812-9033
satish.laroia@amide

Publicity & Program
Michael R. Chernick Ph.D.
Novo Nordisk Pharmaceuticals
100 College Road West
Princeton, NJ 08540
(609) 919-7761
Fax No.: (609) 987-3936
mikc@nnpi.com

Program Committee

Dr. Alfred H. Balch
Novartis Pharmaceuticals
59 Route 10
E. Hanover, NJ 07936-1080
(973) 781-7639
Fax No.: (973) 781-6498
fred.balch@pharma.novartis.com

Dr. Nandita Biswas
GlaxoSmithKline
1250 S Collegeville Road
UP 4310, PO Box 5089
Collegeville, PA 19426
(610) 917-7194
Fax No.: (610) 917-4107
nandita_biswas-1@gsk.com

Dr. Ivan Siu Fung Chan
Merck Research Laboratories
P.O. Box 4 Mail Stop UNA-102
West Point PA 19486
(484) 344-3391
Fax No.: (484) 344-7105
ivan_chan@merck.com

Professor J. Stuart Hunter
503 Lake Drive
Princeton NJ 08540-5632
(609) 924-5644
Fax No.: (609) 683-8756
stuhunt@bellatlantic.net

Jacqueline Kennedy
Wyeth-Ayerst Research
P.O. Box 42528
Philadelphia, PA 19101
(484) 865-2083
Fax No.: (484) 865-0066
Kennedj1@war.wyeth.com

***Walter R. Young has chaired the conference for thirty-two consecutive years.**

December 10, 2001 8:30 – 11:30 AM

Session A

Regression Modeling Strategies Ω

Speaker: Professor Frank E. Harrell Jr.
University of Virginia
Moderator: Nandita Biswas

Regression models are frequently used for hypothesis testing, estimation, and prediction in a multitude of areas. Models must be flexible enough to fit nonlinear and nonadditive relationships while avoiding overfitting and the resulting failure of the model to accurately predict new observations. Some of the topics covered include using regression splines to relax linearity assumptions, perils of variable selection and overfitting, where to spend degrees of freedom, shrinkage, imputation of missing data, data reduction, and interaction surfaces. A default overall modeling strategy will be described. This is followed by methods for graphically understanding models (e.g., using nomograms) and using resampling to estimate a model's likely performance on new data. The methods covered in this tutorial apply to almost any regression model, including ordinary least squares, logistic regression models, and survival models.

Session B

Modeling Variance and Covariance Structure in Mixed Linear Models Ω

Speaker: Ramon C. Littell
University of Florida
Moderator: Jackie Kennedy

Mixed models contain terms for both fixed and random effects. These effects are used to model data in which observations cannot reasonably be assumed independent. Commonly occurring examples include industrial split-plot-type experiments and pharmaceutical studies with repeated measures. The usual primary objective in such studies is to make inference about fixed effects. The covariance structure of the data must be considered in order to obtain valid inference about fixed effects. Appropriate standard errors of estimates are needed for confidence intervals and tests of hypotheses. In addition, the covariance structure may be required in order to compute efficient fixed effect estimates using maximum likelihood or generalized least squares. Covariance structure modeling begins with identifying the experimental or sampling units. Graphical methods can reveal variance and covariance trends, and information criteria are useful for selecting analytical forms of structure.

Monday Lunch (On Your Own) 11:30 AM - 1:00 PM

1:00 - 4:00 PM

Session C

Bayesian Computation and its Application to Non-linear Classification and Regression

Speaker: Professor Bani K. Mallick
Texas A&M University
Moderator: Nandita Biswas

Basic Bayesian modeling and computation techniques will be introduced. Theory and applications of Markov chain Monte Carlo (MCMC) techniques will be discussed. Usual MCMC techniques will be extended in the situation when the dimension of the model is unknown. This is known as reversible jump MCMC. This algorithm will be exploited to obtain automatic Bayes estimates of curves. Trees and surfaces to perform non-linear regression and classification will also be discussed.

Session D

Analysis of Covariance: Repeated Measures and Some Other Interesting Applications Ω

Speaker: Professor George A. Milliken
Kansas State University
Moderator: Fred Balch

The use of analysis of covariance to analyze data sets consists of selecting an adequate form of the covariate part of the model and then compare the levels of the treatments. When the data are from a repeated measures design, an additional step in the process is to select an appropriate covariance structure to model the correlations among the repeated measurements. A strategy for selecting both the covariance and covariate parts of the model is described and some examples are discussed where Proc Mixed of the SAS® system is used to carry out the computations. Other problems encountered during the analysis of covariance such as change from base line and using the covariate to form blocks are discussed.

Session Titles with an Omega (**Ω**) are based on a book which is available from the conference.

December 11, 2001 8:30 – 11:30 AM

Session E

Statistical Methods for Clinical Trials Ω

Speaker: Mark X. Norleans, M.D., Ph.D.
The National Cancer Institute
Moderator: Michael Chernick

Due to confounding in comparing individual patients, the logical basis of clinical studies is comparable groups of patients. The challenge is to control confounding. The main techniques in measurement for characterization of groups of patients are data visualization and summary measures. The techniques for setting up comparable treatment groups and estimating a sufficient quantity of observations include randomization, stratification, blinding, choice of controls, and appraisals of study sensitivity and stability. The focus on integration of clinical studies is quality control and demonstration of consistency and heterogeneity. The statistical theory of Neyman and Pearson will be critically reviewed and regression techniques streamlined. The concept of errors, multiplicity, p-value, testing for equivalence, statistical power, the use of mathematical distributions, and the definition of random and fixed effects will be mentioned. The speaker will also showcase the maximum likelihood technique in the original sense of Ronald A. Fisher, and how to use simple regression techniques to analyze clinical data in a meaningful way. The speaker will demonstrate how to use the LIMU technique to streamline a class of regression models, including generalized mixed linear models, GEEs, generalized linear models, mixed linear models and the analysis of variance across studies. He will discuss techniques for analyzing survival and missing data, center-treatment interaction, average and individual response profiles.

Session F

Experiments: Planning, Analysis and Parameter Design Optimization Ω

Speaker: Professor Jeff Wu
University of Michigan
Moderator: Walter R. Young

Modern tools in design and analysis of experiments will be described. These include robust parameter design for product/process improvement, choice of optimal fractional factorial designs using minimum aberration and related criteria, choice of orthogonal arrays, modeling and analysis strategies including graphical plots and exploitation of interactions. It will be divided between methodologies and illustration with real experiments. Its target audience includes practicing statisticians, engineers, experimental scientists and academics. A background in basic regression and analysis of variance is assumed. No prior background in experimental design is required.

Tuesday Lunch (On Your Own) 11:30 AM - 1:00 PM

1:00 - 4:00 PM

Session G

Sequential Clinical Trials: Design, Monitoring & Analysis

Speaker: Vlad Dragalin, pH, GlaxoSmithKline
Moderator: Nandita Biswas

Sequential Clinical Trials (SCT) provide a means to balance the ethical and economical advantage of stopping a study early against the risk of an incorrect conclusion. The design, conduct, and analysis of a sequential clinical trial are necessarily more involved than that for a clinical trial in which the data would only be analyzed at the end of the study. In this tutorial, we present the additional issues that must be considered when conducting a sequential clinical trial. Emphasis is given to the statistical design issues: fundamental model and its applications, choice of test statistics, group sequential stopping rules, evaluating the design. Flexible monitoring methods such as error-spending, adjusting stopping boundaries, changing the number and timing of interim analyses, but maintaining operating characteristics, are described. Methods for analysis at termination of a SCT, producing valid p-values, bias adjusted estimates and exact confidence intervals, are discussed. Available Software for Design, Monitoring and Analysis of SCT: EaSt 2000, PEST 4.0 and S+SeqTrial are compared.

Session H **Ω**

Multiple Comparisons for Making Decisions

Speaker: Professor Jason C. Hsu
Ohio State University
Moderator: Michael Chernick

The objective of this tutorial is to cover the proper formulation, derivation, and execution of multiple comparisons in order to make correct decisions in a variety of statistical problems. Multiple comparisons are used in many areas of application, including: (1.) Equivalence testing, such as bioequivalence testing in support of an Abbreviated New Drug Application (ANDA); (2.) Efficacy testing of a drug in support of a New Drug Application (NDA) when there are multiple (primary and co-primary) endpoints; (3.) Finding the maximum tolerated dose (MTD) in Phase II clinical trials as well as environmental toxicity studies; (4.) Finding the minimum effective dose (MED) in a dose-response study; (5.) Mapping the gene of a disease using linkage analysis. Using these five examples, the tutorial will cover: (1.) Choice of family of null hypotheses to test; (2.) Control of error rates (a) Per comparison (b) Experimentwise (c) Familywise (d) False discovery (e) Incorrect decision (f) Confidence level; 3. Construction of tests and confidence sets (a) Union-intersection testing, (b) Closed testing (c) Intersection-union testing (d) Partitioning of parameter space (e) Stepwise testing. While theory will be covered, emphasis will be in the context of how they can be applied to the above five applications.

Session Titles with an Omega (**Ω**) are based on a book which is available from the conference.

December 12, 2001 8:30 – 11:30 AM

Session I

Simultaneous Monitoring and Adjustment Ω

Speaker: Professor J. Stuart Hunter, Princeton University

Moderator: Walter R. Young

A process may be declared to be under statistical control when its deviations from target are white Gaussian noise having minimum variance. Since no process is ever truly stable, acquiring and then maintaining these ideal conditions requires constant monitoring and adjustment. Automatic process controls are designed to meet these objectives but not all processes can be automated. Thus both monitoring and adjustment require tools useful to those working on the production floor. The Shewhart charts combined with Box-Jenkins charts fulfill this need. These charting methods will be reviewed. We will find that the Box-Jenkins adjustment chart and bounded adjustment chart are exactly equivalent to automatic integral feedback control. Simple modifications make them equivalent to proportional-integral (PI) feedback control. PI control is required whenever process inertia slows the consequences of adjustment. Changing the frequency and size of adjustments, the choice of sampling interval and the role of adjustment costs are then discussed. The lectures draw upon the final chapters of the text "Statistical Control and Monitoring by Feedback Adjustment", by Box and Luceño.

Session J

Applied Logistic Regression Ω

Speaker: Professor Stanley A. Lemeshow

Ohio State University

Moderator: Jackie Kennedy

This tutorial introduces the use of the logistic regression model in medical and epidemiologic research. Topics to be covered include estimation and interpretation of the coefficients in the logistic regression model and assessment of model performance. Relevant statistical software packages for the analysis of data will be discussed. The latest advances will be given from the second edition of the book with the same title by David Hosmer and the speaker.

Wednesday Lunch (On Your Own) 11:30 AM - 1:00 PM

1:30 - 4:30 PM

Session K

Permutation Methods: A Distance Function Approach Ω

Speaker: Professor Paul W. Mielke, Jr.

Colorado State University

Moderator: Walter R. Young

This tutorial describes advantages of statistical procedures based on alternative distance functions. Specifically the choice of ordinary Euclidean distance rather than the more commonly used squared Euclidean distance has substantial gains in robustness. Also emphasized is the use of coupled rather than decoupled statistical procedures with examples taken from multivariate analyses and regression. Exact and approximate resampling and moment inference procedures are discussed. Of interest in multivariate analyses are the sensitivity differences between Euclidean and Hotelling commensuration. Examples involving analyses of autoregressive patterns, categorical data, cyclic data, rank order statistics, spatial regularity, and runs with two or more types of objects are included. Alternative permutation regression analyses for experimental designs and prediction are presented and compared with existing methods. Permutation methods for goodness-of-fit, multidimensional contingency tables, and multisample homogeneity are considered, including discrete and continuous data methods for both goodness-of-fit and multisample homogeneity methods.

Session L

Approaches to the Analysis of Microarray Data and Related Issues

Speakers: Professors Elisabetta Manduchi and Warren Ewens

University of Pennsylvania

Moderator: Fred Balch

This is a tutorial on high throughput gene expression data generated using microarray technologies. The speakers will discuss how the data are generated, issues and approaches to image quantification and data preprocessing (including normalization), questions these data can help to address and various analysis methods which have been employed to address these questions. Finally, if time permits, some data management issues for this kind of data might be discussed as well. As a separate topic, some of the statistical aspects of BLAST (Basic Local Alignment Search Tool; A tool for assessing sequence similarity and assigning a level of significance to this similarity) will also be discussed.

Session Titles with an Omega (**Ω**) are based on a book which is available from the conference.

TWO SIMULTANEOUS SHORT COURSES

GENERAL COURSE INFORMATION

Registration includes (1) buffet ticket each day; (2) two refreshment breaks each day; (3) copies of overheads and handouts and; (4) the textbook for Measurement Error in Nonlinear Models. No registrations will be accepted without payment in full. Government employees may request to be invoiced at our on-site fee. Courses may be canceled due to insufficient registration in which case tuition will be refunded:

SCHEDULE

8:30 – 10:00 Lecture 10:00 – 10:30 Break 10:30 – 12:00 Lecture 12:00 – 1:00 Lunch 1:00 – 2:30 Lecture 2:30 – 3:00 Break 3:00 – 4:30 Lecture

Proteomics and Genomics Technologies and Their Analysis

Since the improvement of sequencing technologies, it has become possible to identify proteins and nucleotide sequences. This has lead to an information explosion in which large databases of proteins have been sequenced, along with the encoding DNA/RNA. Subsequently microarrays with many of the genes in a selected number of species have been manufactured. Levels of gene expression can be monitored over the course of an experiment for cells or tissue from animals or humans.

We will offer, as a package, two one-day short courses to cover the essentials in this area. Professor Warren Gish, one to the co-authors of the BLAST sequence alignment program will present "Challenges Posed by the Human Genome Project" while Professor Kathleen Kerr, a well-known lecturer, will speak on Design and Analysis of Spotted Microarrays". While we encourage all statisticians to attend both days, the courses are available separately as well.

December 13, 2001

Experimental Design and the Statistical Analysis of Spotted Microarrays

Professor Kathleen Kerr, University of Washington

Moderator: Dr. Fred Balch

Spotted cDNA microarrays are a powerful and cost-effective tool for high-throughput analysis of gene expression. Microarrays measure the relative expression levels of thousands of genes in two or more cell populations. As the potential of this technology has become apparent, many important and interesting statistical issues persist. Multiple sources of variation are present in any microarray experiment, and the data are inherently "noisy." Therefore, sound statistical techniques are essential to compute unbiased estimates of relative expression from microarray results. A confidence interval should accompany every estimate so that one can draw conclusions from the study.

This course is planned for individuals with a solid background in classical statistical topics. Experience with nonparametric techniques, such as bootstrapping, and experimental design is helpful but not required. No particular expertise with microarray data is expected. Statistical techniques for microarray data to be covered include:

- Data transformations: log transform, "shift-log" transform, loess transform, rank invariant transform.
- Analysis of variance models for microarray data: model selection and diagnostics, quality control.
- Nonparametric methods to yield p-values and/or confidence intervals.
- Statistical inference for higher-order analyses such as clustering.

Microarray experiments are inherently multi-factorial and represent a large investment of time and resources. The quality of the results from any experiment depends on the experimental design. This course will emphasize principles of experimental design and their implications for microarray experiments. The mathematical connection between microarray designs and classical block designs will be derived. No previous expertise in experimental design will be assumed. Design topics include:

- Confounding.
- Principles of block design with emphasis on incomplete block designs.
- Robustness and other design properties.

Microarrays are a young technology and there are no textbooks in print on the statistics of microarrays. Many of the topics to be covered are contained in papers. Copies of the following papers will be given to registrants:

M. Kathleen Kerr, Gary A. Churchill (2001). Statistical Design and the Analysis of Gene Expression Microarrays, Genetical Research 77:123-128.

M. Kathleen Kerr, Mitchell Martin, Gary A. Churchill (2000). Analysis of Variance for Gene Expression Microarray Data, Journal of Computational Biology 7:819-837.

M. Kathleen Kerr, Gary A. Churchill (2001). Experimental Design for Gene Expression Microarrays, Biostatistics 2:183-201.

December 14, 2001

Challenges Posed by the Human Genome Project

Professor Warren Gish, Washington University in St. Louis

Moderator: Dr. Fred Balch

The Human Genome Project is producing molecular sequence data at a high rate and from a variety of organisms, where the long-term challenge is to interpret these data meaningfully and completely. Conservation of genetic information over evolutionary history allows intra- and inter-species sequence similarity to be used to identify candidate genes and gene features in these data, and to ascribe function. Various incarnations of the BLAST (Basic Local Alignment Search Tool) algorithm and its accompanying statistics are frequently used in such efforts to interpret the data. Statistical methods are essential to narrowing the focus of human attention to the most likely features to be of biological interest, yet nonrandom characteristics and errors in the data often intercede to make this difficult. This course will cover basic information theory, the BLAST algorithm and its accompanying statistics, the kinds of sequence data and resources that are available, sources of error and ambiguity, and techniques used to avoid statistical pitfalls.

This course is intended for individuals with at least a passing familiarity with DNA and protein sequences and the genetic code. Familiarity with sequence alignment by dynamic programming methods such as that of Smith and Waterman (1981) will be helpful but not required.

Topics covered will include:

- Shannon's entropy and relative entropy
- analytical interpretation of ungapped alignment scores using the method described by Karlin and Altschul (1990)
- the BLAST algorithm (Altschul *et al.*, 1990) and implementations
- both Poisson and Karlin-Altschul (1993) "Sum" statistics for the joint interpretation of multiple alignment scores
- empirical interpretation of gapped alignment scores using the "Island" method of Altschul *et al.* (2001)

Altschul, SF, Gish, W, Miller, W, Myers, EW, and DJ Lipman (1990) Basic Local Alignment Search Tool. J. of Mol. Biol. **215**:403-10.

Altschul, SF, Bundschuh, R, Olsen, R, and T Hwa (2001). The estimation of statistical parameters for local alignment score distributions, Nucleic Acids Research **29**(2):351-61.

Karlin, S, and SF Altschul (1990)..Methods for Assessing the Statistical Significance of Molecular Sequence Features by Using General Scoring Schemes Proc. Natl. Acad. Sci. USA **87**:2264-68.

Karlin, S, and SF Altschul (1993) Applications and Statistics for Multiple High-Scoring Segments in Molecular Sequences. Proc. Natl. Acad. Sci. **90**:5873-7.

Smith, TF, and MS Waterman (1981) Identification of Common Molecular Subsequences. Mol. Biol. **147**:195-7.

December 13, 2001

Measurement Error in Nonlinear Models

Professor David Ruppert, Cornell University

Moderator: Dr Ivan S. F. Chan

The field of measurement error modeling in linear regression, also known as errors-in-variables, has been a well-established field since at least the 1950's. In the early 1980's, researchers became increasingly aware that the problem of measurement error was not restricted to linear models, but was equally important in areas such as generalized linear models, nonlinear regression, change-point models, etc.

This topic began slowly, with only a handful of important papers being written in the 1980's. In 1987, the National Cancer Institute sponsored a workshop in measurement error modeling, which had the direct effect of bringing many researchers into the field, and led to an explosion of work. There have been many new areas where measurement error has been shown to be important, and many new statistical methods developed to address problems in the new areas.

There are four major purposes of this short course:

1. To introduce the problem of measurement error in nonlinear models, and especially for the special case of generalized linear models.
2. To review material from the linear regression area,
3. To present a broad overview of the new methods that have been developed to meet the new challenges.
4. Present examples of applications in fields such as in nutrition, radiation dosimetry, epidemiology.

Participants in the short course should have a good understanding of linear and logistic regression, and some familiarity with generalized linear models. Familiarity with likelihood and Bayesian techniques will enhance appreciation. The text is *Measurement Error in Nonlinear Models* (1995) by Carroll, Ruppert, and Stefanski.

1. **Problem of Measurement Error**	2. **Linear Regression**	3. **Two Simple General Methods**	4. **Structural Methods**
Examples	**P**rediction	**S**IMEX as a graphical tool	**T**he basic likelihood function
Types of error models	**M**issing data analogues	**R**egression calibration (single imputation)	**L**ikelihood methods
Types of data	**T**he effects of measurement error	as an analytical tool.	**B**ayesian methods using Gibbs sampling
Functional and structural modeling	**A**re errors Berkson or classical?		
	Are errors are additive or multiplicative?		

REGISTRATION

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Challenges Posed by the Human Genome Project	$325	$375	$425*	_____
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*On-site registration requires advance notification that you intend to register. ** Course registration includes text.

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Conference Registration Required to Order Books

No. of Copies	PUBLISHER *Title* – Author	List	Site Price
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_____	*Multiple Comparisons: Theory and Methods* – Hsu	$60	$51
_____	*Analysis of Messy Data: Analysis of Covariance, Volume 3* – Milliken and Johnson	$70	$59
_____	*Measurement Error in Nonlinear Models* – Carroll, Ruppert, and Stefanski	$70	$59
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_____	*SAS Systems for Linear Models, 4th Edition* - Littell	TBD	TBD
	SPRINGER - VERLAG		
_____	*Permutation Methods: A Distance Function Approach* – Mielke and Berry	$75	$58
_____	*Regression Modeling Strategies with Applications to Linear Models, Logistic Regression, and Survival Analysis* - Harrell	$80	$61
	WILEY		
_____	*Applied Logistic Regression, 2nd Editon* – Hosmer and Lemeshow	$90	$67
_____	*Experiments: Planning, Analysis, and Parameter Design Optimization* – Wu and Hamada	$95	$71
_____	*Statistical Control: By Monitoring and Feedback Adjustment* – Box and Luceño	$100	$74

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TRAVEL TO THE CONFERENCE

AIR: Fares are generally lower to AC than to Philadelphia. A bus that provides service to all casinos meets all flights into AC. From Philadelphia International Airport, one can take SEPTA to 30th Street and NJ Transit to AC, but this will take more than two hours. Limousine service is also available but this is rather expensive. Spirit, (800) 772-7117, a discount airline, provides service to AC.

RAIL: NJ Transit has relatively frequent local (6 stops) service into Philadelphia connecting with Amtrak and SEPTA at 30th Street. Free shuttle busses meet all trains and provide direct service to all casinos.

BUS: Check your local paper or call the casino bus transportation departments for AC transportation information. There may be a casino bus trip from your local neighborhood as some of these busses travel as far as 200 miles. Most allow you to return on a different day for a charge or a space available basis. Cost of the trip will be offset by casino cash back rebates and other offers. One may take a bus to any casino, collect their coins and coupons and use a jitney to get to Resorts. Greyhound has service directly to Resorts with a rebate, allowing you to return on a different day, from a number of cities, e.g., Philadelphia and NYC.

DRIVING: Many casinos offer cash rebates and/or merchandise, food discounts, etc., in exchange for showing a parking ticket, same day toll receipt, airline or train ticket and/or casino hotel key. Check your local Sunday paper before leaving and if you're in other casinos, check their promotion booths. To get to Resorts from the Garden State Parkway, NJ Turnpike or Philadelphia take the AC Expressway. At its end, turn left on Pacific and turn right on North Carolina. Drive into the Resorts garage on your left. There is a $2 per day fee charged by AC that will allow you to casino hop until 6:00 AM the following morning. However, if you leave your car in the garage for the duration of the conference, there is only a one time $2 fee.

INFO: For maps, schedule of events, casino shows and general tourist info, call the AC Convention and Visitors Bureau at (888) 228-4748.