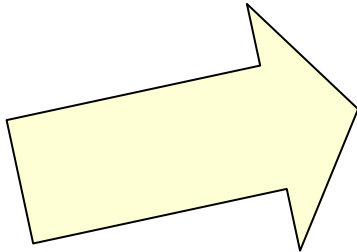


ASAP Newsletter

The Philadelphia Chapter of the
American Statistical Association



May, 2003



<http://www.amstatphilly.org/>

Check it out!

PRESIDENT'S CORNER

Summer is on the way and it is time for our **summer short course**. The topic for this year's course is [Flexible Design and Monitoring of Clinical Trials](#). It will be taught by Prof. Cyrus Mehta and held on Tuesday, July 8, 2003 (see further details, including information on registration, on pages 2-3 of this newsletter). Seating is limited so please register early!

I am pleased to inform everyone that **Boris Iglewicz** (Temple University) received the 2003 Don Owen Award on Friday, April 4 at the Conference of Texas Statisticians. As was mentioned in the February 2003 newsletter, this award is presented by the San Antonio Chapter of the ASA to a statistician for excellence in research, statistical consultation, and service to the statistical community. Congratulations Boris!

I would like to extend a special thank you to the chapter members who participated as judges for several ASAP sponsored awards at the **Delaware Valley Science Fair**. It was a fun day and those who participated found it to be a rewarding experience. Hopefully we can continue to participate in future years.

Ballots for electing 2003-2004 ASAP officers are being sent along with this newsletter (see pages 8-9 for directions on how to cast your vote). I have enjoyed serving as Vice President and then President of our Chapter and would encourage others to consider running in future elections. Thank you to the other members of the Executive Committee for their support of our chapter.

Looking forward to seeing you on July 8th.

~ Kim DeWoody

CALENDAR OF EVENTS

Monday, June 16:	New Jersey ASA, 24 th Spring Symposium
Monday, June 23:	2003-2004 ASAP Officer <u>Ballots Due</u>
Monday, June 30	<u>Registration deadline</u> for Summer short course
Tuesday, July 8:	Summer short course (new officers announced)
Friday, October 31:	11 th Merck-Temple Conference

**ASAP SUMMER SHORT COURSE:
“FLEXIBLE DESIGN AND MONITORING OF CLINICAL TRIALS”
WITH CYRUS R. MEHTA, PH.D. (HARVARD / CYTEL)**

DATE and TIME:	Tuesday, July 8, 2003, 8:00am-4:15pm	
LOCATION:	Holiday Inn, 432 Pennsylvania Ave, Fort Washington, PA (1-800-339-0209)	
LUNCH DETAILS:	PROGRAM SCHEDULE	
<u>Deli Express Buffet</u>	TIME	ACTIVITY
soup du jour; pasta salad;	8:00 - 8:45	Meeting/short course check-in (coffee, tea, danish)
tossed garden salad; potato	8:45 - 9:00	Introduction and election results -- <i>Kim DeWoody (President, ASAP)</i>
salad; sliced roast beef, ham,	9:00 - 10:30	Teaching Session I
and turkey; tuna salad; sliced	10:30 - 10:45	Break (coffee, tea, danish)
cheeses; breads and rolls;	10:45 - 12:15	Teaching Session II
cakes; coffee and tea	12:15 - 1:15	Lunch
	1:15 - 2:45	Teaching Session III
	2:45 - 3:00	Break (coffee, tea, soda, cookies)
	3:00 - 4:15	Course Review/Question and Answer Session
Cost: \$75 per person (\$25 for full-time students)		

Registration: Please **RSVP by Monday, June 30** to Risa Cuebas (484-865-2071 or cuebasr@wyeth.com). SPECIFY COMPANY/INSTITUTION, AND IF YOU ARE A FULL-TIME STUDENT. Send checks payable to “ASAP” to Ms. Risa Cuebas, COL RC-3258, Wyeth Research, P.O. Box 42528, Philadelphia, PA 19101. You may also pay by cash or check at the meeting, but PLEASE REGISTER IN ADVANCE to assist us with a head count.

Directions: From the PA Turnpike, take Exit 26 – Fort Washington. After the tollbooth, follow the left-hand lane under the overpass. (DO NOT TAKE THE ROUTE 309 RAMP.) The hotel is 1/8 mile on the left. From Route 309, take the Fort Washington exit. (DO NOT TAKE THE EXIT FOR THE PA TURNPIKE.) Exiting will put you onto Pennsylvania Avenue. Stay in the left-hand lane. The hotel is 1/8 mile on the left.

Abstract

As an alternative to the standard fixed-sample design of clinical trials it is now possible to monitor an on-going trial at administratively convenient time points, gain early information from the accruing data, and adjust the future course of the trial. Possible mid-course adjustments include early termination of the trial for futility, early termination for efficacy, changes in sample size and changes in the length of follow-up. Thereby trial sponsors can increase their chances of identifying positive compounds earlier and can allocate resources more optimally across their product development program. Designing clinical trials with planned interim monitoring is a complicated task, however, requiring intimate familiarity with the statistical methodology of group sequential inference and an understanding of the regulatory perspective concerning the potential for introducing bias or for

inflating the type-1 error. This one-day workshop will cover the statistical methods of group sequential inference that make it possible to monitor trials, terminate early and make sample size adjustments while preserving both power and type-1 error rates. The presentation will be at a conceptual rather than technical level and it will be illustrated by numerous examples and simulations of actual clinical trials with the help of the EaSt software. Specific topics include:

- efficacy stopping boundaries
- futility stopping boundaries
- non-inferiority stopping boundaries
- spending functions
- conditional power
- repeated confidence intervals
- inference following early stopping
- special characteristics of time-to-event studies
- adaptive designs featuring sample-size re-estimation

Congratulations to [Dirk Moore](#) (Temple University) for winning free entry to summer short course! Dirk won this prize at the raffle held at our Spring Meeting on March 14 by suggesting a short course topic.

Biosketch

Cyrus Mehta, Ph.D. is an Adjunct Professor of Biostatistics in the Department of Biostatistics at the Harvard University School of Public Health, where he has taught since 1979. Previously he taught at the University of Pittsburgh. Dr. Mehta has published over 65 papers in professional journals including JASA, Biometrika, and Biometrics. He received the 1987 George W. Snedecor Award from the American Statistical Association with two co-authors. In 1995 Dr. Mehta was elected a Fellow of the American Statistical Association. He received his Ph.D. from MIT in 1973.

For the past 15 years Dr. Mehta has concentrated his research activities on developing permutational algorithms which can be applied to categorical data analysis, nonparametric tests, power and sample size calculations, the analysis of contingency tables and, more generally, to inference concerning the parameters of regression models for categorical data. The ideas underlying this research span three disciplines: statistics, computer science, and operations research. A second major research interest is in field of group sequential inference for clinical trials. Dr. Mehta is also the Zoroastrian representative on Harvard University's Board of Ministry.

Dr. Mehta is co-founder and President of Cytel Software Corporation, Cambridge, Massachusetts (<http://www.cytel.com>). Cytel's mission is to pursue advanced research in the fields of computational statistics, group sequential inference, toxicological risk assessment, missing data problems and longitudinal data problems, and to convert the fruits of that research into user-friendly software. So far Cytel has developed six statistical packages; StatXact, LogXact, EaSt, Egret, ToxTools and StaTable. In 1998 Cytel received an award from the Massachusetts Technology Development Council for outstanding technology development funded by the Small Business Innovation Research program.

NEW JERSEY ASA
24TH SPRING SYMPOSIUM
June 16, 2003
Embassy Suites, Piscataway, NJ

The topic of this year's spring symposium is "Surrogate Endpoints and Statistical Issues in the Accelerated Approval Process." Distinguished speakers include **Stephen L. George**, Ph.D. (Duke University), **Larry Gould**, Ph.D. (Merck Research Laboratories), **Danyu Lin**, Ph.D. (North Carolina University), and **Richard Pazdur**, MD (CDER). For additional details, please see http://www.stat.rutgers.edu/njasa/SYMPOSIUM_2003_2.pdf.

11TH MERCK-TEMPLE CONFERENCE
Friday, October 31, 2003
Plymouth Meeting DoubleTree Hotel

Registration for the 11th Merck-Temple Conference is now open. Cost is \$80, \$25 for full time graduate students, and reduced rates for persons from Merck, Bristol-Myers Squibb, Aventis, and Wyeth. The Conference will again be held at the Plymouth Meeting DoubleTree Hotel. Registration fee includes continental breakfast, lunch, and breaks. Parking is free. We again have a first rate set of speakers including: **Keith Baggerly** (M.D. Anderson Cancer Center); **Raymond Carroll** (Texas A & M University); **Larry Gould** (Merck Research Laboratories); **Daniel Heitjan** (University of Pennsylvania); and **Michael Hughes** (Harvard University). Payment must be by check, but multiple persons can register with one check. All checks must be received at least three days before the meeting, made out to Temple University (Biostatistics), and sent to Boris Iglewicz, Director, Biostatistics Research Center, Department of Statistics, Temple University, 1810 N. 13th Street, Philadelphia, PA 19122. For Conference details, see upcoming events at www.sbm.temple.edu/~biostat, or contact Boris Iglewicz at boris.iglewicz@temple.edu, or by telephone (215) 204-8637.

DELAWARE ASA SPRING CONFERENCE:
"PROBABLE JUSTICE: STATISTICS AND THE JUDICIARY"
Friday, April 25, University of Delaware, Newark, Delaware

Five prominent speakers covered a variety of topics based on their extensive experience in forensic statistics: **William Fairley** (Analysis and Inference, Inc., Swarthmore, PA) outlined three of his cases to show how statistics can be used to avoid litigation; **Eugene Ericksen** (Temple University) summarized how statistical modeling has been used to estimate undercounted citizens in the U.S. census over the past few decades; **Joseph Gastwirth** (George Washington University) highlighted how epidemiology should be used to properly identify and evaluate risk factors when ascribing product liability; **Seymour Geisser** (University of Minnesota) explained how the FBI's choice of genetic standards may have inappropriately skewed test results to favor prosecution; and **Bruce Weir** (North Carolina State University) described how genetic fingerprints are being developed to be as unique as their old-fashioned namesakes. A sixth speaker, **Patrick Ball** (American Association for the Advancement of Science), who was scheduled to speak about estimating mortality patterns due to political violence, canceled in order to testify in The Hague. Commented host and Delaware ASA President, Joseph Pultz, "A likely story."

DELAWARE VALLEY SCIENCE FAIR AWARD WINNERS!



Kevin Wayns (left) and Allison Skidmore (right) receive their awards from ASAP Newsletter Editor Paul Mange Johansen (center)

On April 3, the Philadelphia ASA Chapter (ASAP) awarded three promising students checks for \$100 each at the Delaware Valley Science Fairs (DVSF). The DVSF, Inc. was founded in 1949 by the Franklin Institute and *The Philadelphia Inquirer*, making it one of the oldest science fairs in this country. The DVSF draws students from 19 counties in southern New Jersey, southeastern Pennsylvania, and Delaware. Eight statistical judges evaluated nearly 1,000 posters across 13 subject areas -- behavioral/social sciences; biochemistry; botany; chemistry; computer sciences; earth/space sciences; engineering; environmental sciences; mathematics; medicine/health; microbiology; physics; and zoology -- and gave awards to the students who made the best use of statistics in their independent research project. The winners were: **Allison Skidmore** (8th grade, age 14) from Unami Middle School in Chalfont, PA for her medicine/health project, "Kicking Causes Curves;" **Amanda Greer** (10th grade, age 16) from High Technology High School in Lincroft, NJ for her engineering project, "Classroom Milling Devices and Useable Flour Production;" and **Kevin Wayns** (11th grade, age 16) from Central High School in Philadelphia for his microbiology project, "Residual Pathogen Contamination." In addition, student versions of JMP INTRO software, generously donated by the SAS Institute, were given to Amanda's and Kevin's schools. Finally, certificates and information about ASA and ASAP were given to all three students and their schools. Look for this write-up in the June issue of [Amstat News](#).

AROUND THE HORN IN STATISTICAL EDUCATION

We are fortunate to have a range of university-level statistics programs in and around Philadelphia. Temple University has been consistently producing award-winning students for years. This fall West Chester University will offer its first courses in statistics. Here's a quick overview of what's happening around the horn in statistical education:

University of Pennsylvania: The Center for Clinical Epidemiology and Biostatistics (CCEB) of the University of Pennsylvania School of Medicine offers M.S. and Ph.D. degree programs in Biostatistics. The goal of the two-year M.S. program is to train students in the basic theory and applications of statistical methods, especially as applied to problems in the biomedical sciences. The Ph.D. degree program is designed to train independent researchers in biostatistics applications and methodology. The four- to five-year Ph.D. program includes required courses teaching fundamental skills, methodologies, and principles of biostatistics. Students also are expected to do extensive independent readings, attend seminars, complete a comprehensive analysis of a data set, pass comprehensive written and oral exams, and complete a doctoral dissertation.

Mentoring for M.S. and Ph.D. students is provided by biostatistics faculty. Both degree programs are conducted in collaboration with Wharton's Department of Statistics. Many courses are offered jointly by the two academic units. Research assistantships and fellowships are available, providing full support for tuition and competitive stipends. Those interested in receiving more information and/or an application should correspond with Ann Facciolo / Center for Clinical Epidemiology and Biostatistics / University of Pennsylvania School of Medicine / Blockley Hall, Room 625 / 423 Guardian Drive / Philadelphia, PA 19104-6021 / 215-573-3881 (voice) / 215-573-4865 (fax) / afacciol@cceb.upenn.edu (e-mail).

University of Delaware: The Graduate M.S. Program in Statistics in the College of Agriculture & Natural Resources includes theoretical and applied aspects of statistics with an emphasis on using these skills in real-world statistical problems. Students will receive basic training in theoretical statistics and advanced training in regression, experimental designs, timeseries, spatial statistics, multivariate statistics, logistic regression, and database management. M.S. candidates will participate in the Statistical Laboratory working on applied problems and also are encouraged to participate in an Internship program. For additional information click on <http://ag.udel.edu/departments/frec/statistics/index.htm>.

West Chester University: The Applied Statistics Program at West Chester University has scheduled the first classes in its new Masters and Certificate Degree Programs for the Fall 2003 semester. More information about these courses and the Program can be found at the web site: <http://math.wcupa.edu/~AppliedStatistics>. The course numbers, titles and times are:

STA505	Mathematical Statistics I (Tuesdays 5:45-8:30 PM)
STA511	Introduction to Statistical Computing and Data Management using SAS (Mondays 5:45-8:30 PM)

In addition, in collaboration with Barnett International, West Chester University is offering workforce development funds through the WEDnet Guaranteed Free Training program to those who wish to enroll in the Clinical Research Training. Two new course opportunities include Clinical Research Associate & Clinical Research Coordinator Training, and Clinical Data Management Training. Applications for this Free Training must be received by July 15, 2003. For further information please contact Patricia Grande at 800.856.2556 extension 2610 or email her at patricia.grande@parexel.com.

Temple University: For information click on www.sbm.temple.edu/~biostat.

Villanova University: For information about the Department of Mathematical Sciences, click on http://www.math.villanova.edu/degrees/graduate_programs.html.

FROM THE EDITOR: SARS STATS

For the first time in history, a new human disease has rapidly riveted the world's attention. Severe acute respiratory syndrome (aka SARS) is a new form of pneumonia with rates of contagion and mortality roughly equivalent to existing forms of pneumonia. It is reasonable to ask whether the global responses are proportionate: do the health risks justify recommendations against travel to areas of highest infection? do the risks justify quarantine? do they justify the marketing and selling of various nostrums and home-remedies? should public health officials be doing more to combat this disease? less? These are questions which statistics can, should, and must play a critical role in answering.

Howard Markel and Stephen Doyle presented the following "Epidemic Scorecard" numbers (world-wide, per year, except for SARS) on the Op-Ed page of the *New York Times* on April 30:

<u>Condition</u>	<u>New Infections</u>	<u>Deaths</u>
Cardiovascular Disease		17,000,000
Tobacco-related		3,500,000
AIDS	5,500,000	3,100,000
Tuberculosis	8,000,000	2,000,000
Diarrheal Diseases	2,700,000,000	1,900,000
Motor Vehicle		1,260,000
Malaria	300,000,000 to 500,000,000	1,000,000
Hepatitis B	10,000,000 to 30,000,000	1,000,000
Measles	30,000,000	~900,000
Influenza	3,000,000 to 5,000,000	250,000
Yellow Fever	200,000	30,000
Dengue Fever	20,000,000	24,000
 SARS (in 180 days)	 5,462	 353

These figures suggest that SARS is a threat to be taken seriously. But while it is important to learn as much as possible about this new threat, it is equally important not to forget about existing threats. These figures also suggest that some of the attention now focusing on SARS may be well-spent combatting conditions threatening more people worldwide. Despite effective and safe vaccines, treatments, and programs against many of these conditions, they continue to plague humanity.

David Baltimore concluded his April 28 editorial in the *Wall Street Journal* ("SAMS -- Severe Acute Media Syndrome?") by noting, "As the SARS overreactions suggest, the era in which public alarm can soar out of proportion to genuine risk is only beginning." If we are to realize our mission as statisticians -- "to promote excellence in the application of statistical sciences across the wealth of human endeavor" -- we have a responsibility to help put these numbers in perspective in order to align reactions with risks, and to allay unreasonable fears.

--Paul Mange Johansen

ELECTIONS FOR 2003-2004 ASAP OFFICERS

The American Statistical Association, Philadelphia Chapter (ASAP) has four elected positions: President; Vice-President; Secretary; and Treasurer. The term for these positions runs from July 1, 2003 through June 30, 2004. The primary responsibilities of the elected officers include organizing the fall and spring chapter meetings, as well as the summer short course. Elected officers may also appoint other executive positions, such as Chapter Representative, Webmaster, Outreach Officer, and/or Newsletter Editor. Additional activities may be initiated as creativity and time permit.

Biosketches of all candidates follow on the next page. Accompanying this newsletter you will find a ballot with detailed instructions. Ballots must be filled out and returned as instructed on the ballot by **Monday, June 23**. Three people served on this year's Elections Committee: Kim DeWoody (outgoing ASAP President); Paul Johansen (ASAP Newsletter Editor); and Debbie Panebianco (ASAP Webmaster). Results will be tallied by Paul Johansen and verified by Debbie and Kim. Results will be announced on Tuesday, July 8 at the ASAP Summer Short Course and by email. Thank you in advance for your participation in this important chapter activity!

Candidate for PRESIDENT:

Charles Tan is a Senior Biometrician at *Merck Research Laboratories* and has worked in the pharmaceutical industry for over 8 years. During this time he has supported basic and preclinical research, analytical development, quality management, and manufacturing. He is a 2001 winner of W. J. Youden Award in Interlaboratory Testing from the American Statistical Association (www.amstat.org/pressroom/youden.html). He is currently a member of the Biostatistics Expert Committee of USP (United States Pharmacopeia). He received a Ph.D. in Statistics from Temple University in 1998.

Candidates for VICE PRESIDENT:

Amit Bhattacharyya is currently Associate Director, Statistical Sciences at *GlaxoSmithKline*, where he leads two groups of statisticians. He has been a technical Statistician and a Statistical Manager at GSK in the US and overseas. Amit is currently the Joint Secretary of the ASA-Biopharmaceutical section, and has organized JSM sessions and training courses for new statisticians in the industry. Amit received a Ph.D. in Statistics from University of Maryland (1994), and an M.Sc. in Statistics from the University of Calcutta, India (1989).

Diane Miller is Senior Director, Biostatistics and Data Management Department, *GlaxoSmithKline* in Upper Merion, Pa. She has worked in the pharmaceutical industry for over 20 years. She served as Program Chair for Statistical Consulting Sub-Section of ASA (1995) and Corresponding Secretary of the Philadelphia Chapter of the ASA (1995-1997). Diane received a Ph.D. in Quantitative Genetics and Statistics from The Ohio State University in 1982.

Candidate for TREASURER:

Michael Mack is a Senior Principal Statistician in clinical research at *Wyeth Research*, where he has worked for 14 years. He was previously a Senior Biostatistician with ICI Pharmaceuticals, an Assistant Professor of Mathematics at Marshall University in West Virginia, a Research Fellow at Carnegie-Mellon University, and a Visiting Assistant Professor of Mathematics at the University of Pittsburgh. He received a Ph.D. in Statistics from Carnegie-Mellon University in 1979. He was first elected Treasurer of the Philadelphia Chapter of the ASA in 2001.

Candidates for SECRETARY:

Lisa Hickey is a Senior Statistician at *Merck Research Labs*, where she works in the Clinical Pharmacology area. She was previously employed at ProMetrics Consulting, Inc. as an Analyst. She received an M.S. in Applied Statistics at Villanova University, and is currently serving as Secretary of the Philadelphia ASA Chapter .

Bob Gagnon is an Associate Director in the Statistical Sciences department at *GlaxoSmithKline*. He has worked as a non-clinical statistician for 16 years, and as an epidemiologist for 1 year, all at GSK. Prior to working as a statistician, he worked for 6 years as a bench scientist. He received an M.S. in Applied Statistics from Villanova University in 1989 and recently completed his Ph.D. at Temple University.

TREASURER'S REPORT

BALANCE FORWARDED (31-Jan-03):	\$2,478.71
INCOME:	
ASA Chapter Dues	
Jan-03	\$ 206.00
separate payment	\$ 8.00
Sub-Total	\$ 214.00
Spring Meeting registrations	\$ 1,465.00
Jan event --Temple student payment	\$ 80.00
Sub Total	\$ 1,545.00
TOTAL INCOME:	\$1,759.00
EXPENSES:	
Spring Meeting Costs (Mar-2003)	
Facility, meals	\$ 2,046.24
Sub Total	\$ 2,046.24
Delaware Valley Science Fair (Apr-2003)	
Awards	\$ 300.00
Certificates, Frames	\$ 116.96
Sub Total	\$ 416.96
Postage	\$ 37.00
Sub Total	\$ 37.00
TOTAL EXPENSES:	\$2,500.20
BALANCE FORWARDED (30-Apr-03):	\$1,737.51

2002 - 2003 ASAP CHAPTER OFFICERS

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* Elected position

**Appointed position

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STATISTICAL HUMOR by Robert Mankoff



"A billion is a thousand million? Why wasn't I informed of this?"

