The American Statistical Association

San Francisco Bay Area Chapter

Since 1928

June 1997

Joint Biostatistics and General Applications Program

"Oncology Clinical Trials: How Are They Different?"

Speaker: Sue Hellmann, M.D. , Chief Medical Officer, Genentech Inc.
Discussant: Kathleen Lamborn, Ph.D., Professor Neurological Surgery, Director UCSF Cancer Center Biostatistics Core

Abstract

The approach to designing and analyzing cancer clinical trials has historically been different from that used for many other disease types.

Three major compounds recently approved for cancer will be outlined: Taxol for breast cancer, CPT-11 for colon cancer, Gemcitabine for pancreatic cancer. Discussion will include the unique features of the trial designs and endpoints used to evaluate these therapies.

Date: Thursday, June 12, 1997

Time:
3:30 - 4:00 PM Refreshments
4:00 - 4:15 PM Business Meeting and Officer Elections
4:15 - 5:15 PM Discussion

Place: Genentech Conference Rm. 5Q, Building 5
499 Point San Bruno Blvd., South San Francisco

Dinner for the speakers will follow at 6 PM

Directions: Refer to enclosed map. You may also access the map and directions on the internet at http://www.gene.com/directions.html.

Officer Candidates for 1997-1998

The chapter's annual business meeting will be held just before the discussion at the June 12 meeting. At that time, elections of next year's officers will be held. So far the nominees are as follows:

President:
Michael Lock
Becton-Dickinson

President-Elect:
Ying Lu
University of California, San Francisco

Vice President for General Applications
Ding Li
Bank of America

Vice President for Biostatistical Programs
Hina Malani
Center for Applied Statistics

Treasurer
Jim Lenihan
Trilogy Consulting Corporation

Secretary
Ann Kalinowski
Failure Analysis Associates, Inc.

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Kathleen Lamborn	Michael Lock	Ding Li	Ying Lu	Jim Lenihan	Ann Kalinowski
(415) 476-8863	(408) 954-2583	(415) 622-0408	(415) 502-4596	(415) 742-0131	(415) 688-7203
lambornk@neuro.ucsf.edu	Michael_Lock@bdis.com	ding@crl.com	ying_lu@rad-mac1.ucsf.edu	jim@sfasa.org	sfamk@fail.com

If you have any other nominees for these positions, please feel free to contact the Chair of the nominating committee, Lauren Schoof, at (510)824-6627.

Newsletter Update

The national organization of the American Statistical Association is often several months behind in forwarding your names and dues to us, so the Chapter instituted the policy of sending newsletters out even to those whose membership has lapsed by our records. However, this policy has resulted in having some persons on our mailing list being not just a few months, but a few years in arrears. Please take the time this summer to make sure that your chapter membership is up-to-date. Chapter dues ($9 for one year regular membership, $3 for one year student membership.) The dues may be paid either along with National dues at the time you renew your ASA membership, or directly to the Chapter by mailing them to Jim Lenihan at 15 Moonlight Court, South San Francisco, CA 94080. This newsletter is the last chapter members will receive for the 1996-1997 year. Over the summer I will update the membership records with the national organization, and will flag members who are in arrears on their September 1997 mailing labels. After the September newsletter, members who are not current on their Chapter dues will be dropped from our mailing list.

ASA Traveling Course in Sacramento

The Sacramento Chapter is sponsoring an ASA Traveling Course on logistic regression, given by Michael Kutner from 9 AM to noon on June 9, 1997 at the Sacramento State University Student Union. Cost for the course is $30. Contact Kathleen Gallagher, President of the Sacramento Chapter at ZKJL73A@PRODIGY.COM for more information.

Open Positions

Gilead Sciences
Foster City

Gilead Sciences is a leader in the discovery and development of a newclass of broad spectrum antiviral therapeutics that may provide powerful new treatments for CMV retinitis, HIV, influenza and other viruses.

Manager, Biometrics

Acting as a team leader for a group of statistical programmers in NDA submissions, you will provide input on automating statistical reporting, design statistical analyses, and write up methodology and results sections of study reports. You will need a Ph.D. and 5 years' pharmaceutical experience. Applied statistical knowledge, experience with NDA submissions, good oral/written communication abilities, SAS programming skills (including macros), and knowledge of database design are required.

Statistical Analyst

You will explore and exploit the relative strengths of SAS and Clintrials 4.0 to prepare and implement an efficient programming infrastructure for automated tracking and reporting for clinical trials. This will include creating a library of SAS macros and resalable tools and maintaining a seamless interface between Clintrials, wordprocessors and SAS and connectivity for remote SAS users. You will also create a GUI report interface for clinical and data management users and provide users the ability to browse CRFs, data listings and summaries. Along with a Masteris in Statistics and 5 years' relevant experience, we require strong skills in these areas: SAS macros; SAS-AF; SAS-EIS; SAS-Graph; SAS-FSP; structured programming; UNIX. Excellent analytical, writing and communication

skills are also essential. Two positions available.

Statistical Programmer

You will perform analyses of clinical trial data, including listings, tabulations, graphical summaries and formal statistical estimates and tests. You will also edit specifications for quality control of data, perform cross study analyses and use SAS macros to automate all of the above functions. We will also rely on you to develop reporting analysis plans for new studies and assist in the preparation of NDAs. Your Master's degree in Statistics should be supported by 3 years of experience demonstrating skill in the following areas: SAS-Stat, SAS-Graph, SAS macros, structured programming, and statistical analysis. Good oral and written communication abilities and analytical skills are required.

Interested candidates should send a resume, indicating position of interest, to: Human Resources, Gilead Sciences, Inc., 333 Lakeside Drive, Foster City, CA 94404, fax (415) 573-4800. Or check our website: www.gilead.com. We are proud to be an equal opportunity employer.

SangStat Medical Corp. Menlo Park

SangStat, The Transplant Company™, is applying a disease management approach to imporve the outcome of organ transplantation. the company's devices, drugs and services form a family of products that address the needs of patients in each stage of transplant care from pre-transplant monitoring to lifetime post-transplant care. SangStat's broad product pipeline is a combination of proprietary and licensed-in products that are in various stages of research, development, and marketing. The company plants to capitalize on this pipeline by developing relationships with key providers and managed care organizations to better integrate the management of the transplant recipient's care to imrove outcomes and lower costs.

Biostatistician/Statistician

We are recruiting a biostatician or statistician with training and experience in clinical research and (ideally) organ transplantation. This person will be part of our clinical development group and report to the Executive Director. Responsibilities will include leading in the development of biostatistical support including study design, biostatistical methodology and analysis (i.e. bioequivalence testing, life table survivival analysis, multivariate analyses, etc.) and collaborating in development of the data management system. In addition, it is desirable for this person to be interested in developing new models for transplant data analysis and testing the validity of new transplant study end points.

Qualifications include a Ph.D. in biostatistics/statistics, or M.S. with clinical trial experience.

Interested persons should call and send a resume to:-

Daniel M. Canafax, Pharm.D.

Executive Director, Clinical Development

SangStat Medical Corp.

1505 Adams Dr.

Menlo Park, CA 94025

phone (415)688-2355

FAX (415)329-9599

Directions to Genentech

From San Francisco:

- Take 101 Freeway south.
- Exit at Grand Ave/South San Francisco
- At the bottom of the ramp, turn left onto Airport Blvd.
- At stoplight, turn left onto Grand Ave. and proceed under freeway to East Grand Ave.
- At the fourth stoplight, turn left onto Forbes Blvd.

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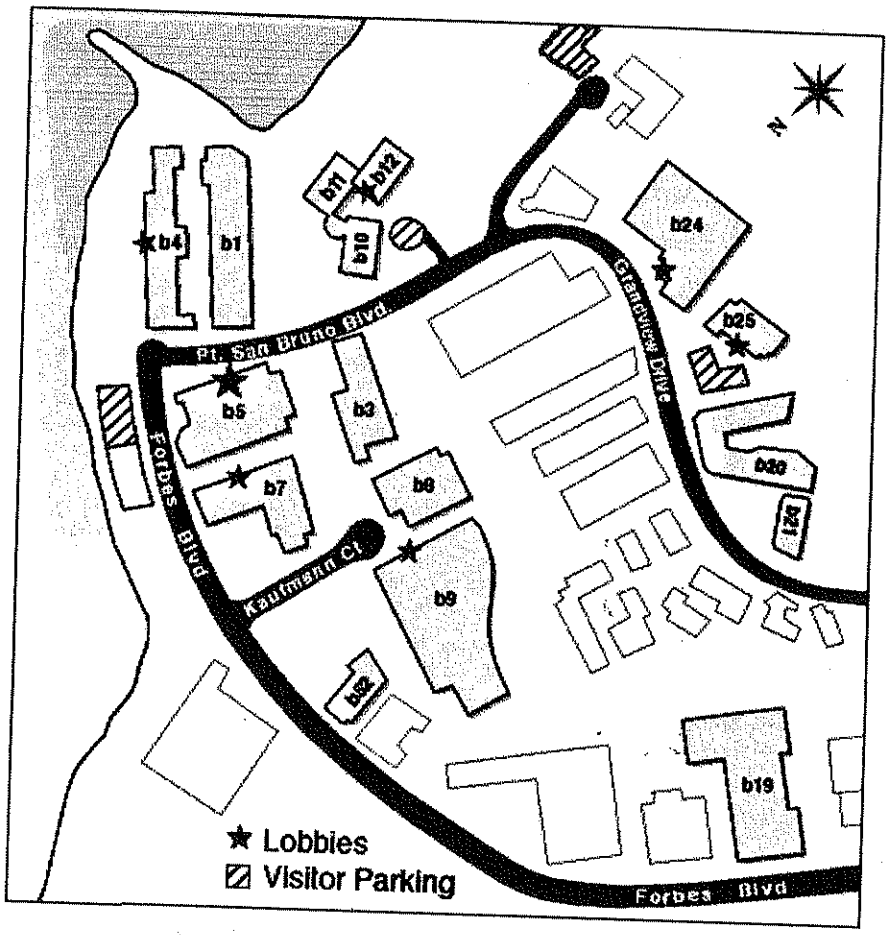
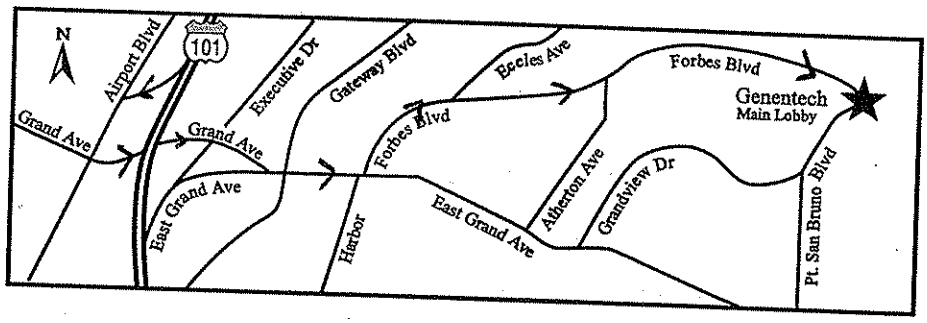
- At the fourth stoplight, turn left onto Forbes Blvd.
- Continue on Forbes Blvd. for 1.3 miles until it terminates at Point San Bruno Blvd.
- Park in the lot on Forbes Ave. across from Bldg. 5 and register in the lobby of Bldg. 5.

From the Peninsula and San Jose:

- Take 101 Freeway north.
- Exit at Grand Ave/ South San Francisco.
- At the bottom of the ramp, turn right onto East Grand Ave.
- At the first stoplight, turn right to continue on East Grand Ave.
- At second stoplight, turn left onto Forbes Blvd.
- Continue on Forbes Blvd. for 1.3 miles until it terminates at Point San Bruno Blvd.

Proceed to the visitor parking lot on Forbes Ave. across from Bldg. 5 and register at the lobby in Bldg. 5.





San Francisco Bay Area Chapter

American Statistical Association

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The American Statistical Association

San Francisco Bay Area Chapter

Since 1928

April 1997

Joint Biostatistics and General Applications Program and Stanford Biostatistics Workshop

"Regression Methods for Data from Epidemiological Studies of Heterosexual HIV Transmission"

Stephen Shiboski
Department of Epidemiology and Biostatistics
University of California
San Francisco, CA

Abstract

Infection outcomes from studies of heterosexual transmission of HIV are often subject to interval or double censoring, posing challenges to estimation and inference. I will present some recent regression approaches for investigating covariate effects and hazard estimation in this setting, using data from three CDC-sponsored studies of transmission in partners of previously infected individuals for examples. In addition, I will discuss inherent limitations of such studies in providing information about important features of the transmission process, such as variations in infectiousness and susceptibility.

Date: Thursday, April 17, 1997

Time: 3:45 - 4:15 PM Coffee
4:15 - 5:15 PM Talk

Place: **Coffee:** Statistics lounge on the third floor

Margaret Jacks Hall, Building 460 in the center of the Outer Quadrangle facing the Oval

Talk: Room 30, Building 200, the History Corner of the Stanford Quadrangle

Dinner for the speaker will follow at 6 PM

Directions: A map of the Stanford campus is available at http://www.stanford.edu/home/visitors/campus-map.html. See the following directions.

Directions to Talk at Stanford:
Park in the lot that surrounds 855 and 857 Serra Street. Be prepared with quarters for parking meters. Marked constraints on parking are enforced until 5 PM.

From 101 take the University Avenue off ramp and head west from the freeway. Stay on University Avenue through Palo Alto. About two miles from 101 the street becomes Palm Drive, and you enter the Stanford campus.

Come up Palm Drive and turn left onto Campus Drive East. Take the third right onto Serra Street. The parking lot that surrounds 855 and 857 Serra Street is on your right.

From 280 get off at Alpine Road and head east (towards the Bay, not the hills). Turn right at the light onto Junipero Serra. Turn left at the second traffic light (intersection of Campus Drive East and Junipero Serra.). In about six blocks, at the corner of Serra Street and Campus Drive East, turn left, and follow the instructions above.

From El Camino Real, turn into Stanford at Palm Drive and follow the instructions above.

To Refreshments and Talk
Walk away from the direction of Campus Drive East, past tennis courts, Arguello Way, and Galvez Street, all on your right, and the Hoover Tower on your left. Almost immediately you come to the corner of the Quadrangle, to Building 200 where Dr. Shiboski's presentation is. To get to the refreshments, continue down the edge of the Quadrangle, past the center, to Margaret Jacks Hall and the Department of Statistics. Take the elevator or walk to the third floor for the refreshments.

Employment ads are now $50 per insertion. Please contact chapter secretary.

OPEN POSITIONS:

Statistician
UCSF Dept. of Medicine
Division of Rheumatology

50-100% effort (depending on experience and salary level. The major duty of this job is to serve as the statistician for an ongoing genetic epidemiology of rheumatoid arthritis project. The project components include longitudinal patient information, physician surveys, genotyping data, radio-graphic data, medical record information, and family histories (i.e., pedigrees). This job requires analysis (e.g., PROC MIXED, GEE macro). This job also required familiarity with PC hardware and software. This individual must have a master's degree in statistics (or a closely related field), or extensive previous statistical analysis experience. Preferred skills include experience or a strong interest in genetic epidemiology, including analysis of family (pedigree) data, and excellent writing skills. Experience with Access (Part of Microsoft Office) and/or Cyrillic (pedigree) software is desirable. Comfort with computer software and hardware upgrades, internet access, and networking is also desirable. This job will involve close interaction with the Principal Investigator, and with other staff involved in data collection, entry and cleaning. Examples of analyses planned for the first six months include: the relationship between genetic factors and long-term clinical outcomes, interactions between genetic and environmental factors and disease susceptibility, and relevance of genotype to clinical decision making.
For further information, contact Lindsey Criswell at Tel: (415)476-9026, FAX:(415)476-9370, or e-mail: lac@itsa.ucsf.edu.

Pacific Research Associates

Los Altos

SAS Programmer

We are a growing consulting firm that offers high-quality research support to the pharmaceutical and biotechnology industries. Our operation is built upon biostatisticians, programmers, and data specialists executing statistical programs designed to analyze clinical trial data. You will assess data accuracy and consistency, identify protocol violations, implement statistical analyses and produce final tables and figures. Qualified applicants should have training equivalent to a BS in a quantitative discipline or equivalent work experience, and 2 years experience in the analysis of clinical data. Must have familiarity with common statistical analyses and extensive knowledge in designing, conducting, analyzing and reporting clinical studies.

As a member of our team you will be responsible for planning writing and of SAS and other software packages used to perform statistical analyses.

Please send your resume to:

Pacific Research Associates

Attn.: Sally Kimball

399 Main Street

Los Altos, CA 94022

Phone (415)917-3660

Fax:(415)917-3683

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Statistician:

In this fast-paced environment, you'll assist project teams within LifeScan in designing test protocols, statistical analysis and presentation of data. Utilizing appropriate statistical and analytical techniques, your problem solving skills will be needed to assist management in making critical decisions.

You will need an MS or Ph.D. in Statistics, or equivalent, with 2+ years' experience in a manufacturing environment or medical device industry. Your knowledge of FDA requirements for 510k submission is desirable. Experience in the design and analysis of clinical trials, sampling plans, design of experiments, and SPC is essential. You must be proficient in SAS, possess excellent written and verbal communication skills, as well as be an experienced project leader and team player. **JOB CODE SFASS97-1.**

Statistical Programmer:

Utilizing your technical skills in Statistics and SAS programming, you will work primarily with statisticians in developing and validating applications within the Statistical Support Group. You will be involved in creating SAS applications for product development, manufacturing support, and clinical studies, as well as assist in statistical analysis of data.

Requires a BS or MS in Statistics, or equivalent, with 3+ years' experience in SAS programming. You must be proficient in SAS STAT, BASE, MACRO, GRAPH, and IML. You must be a proven team player and possess excellent written and verbal communication skills. **JOB CODE SFASS97-2.**

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Inverse Network Technology Inc.

Santa Clara

Inverse Network Technology Inc. provides products and services to

measure end-to-end Internet performance as experienced by real users. We enable the Internet community to improve their quality of service, including reliability and performance. Our customers include four of the top five Internet Service Providers and major Internet-enabled applications vendors, including Intuit and WebTV.

Engineering Job Description

We are looking for full or part time consultant(s) with a strong statistics background. The job could convert to full time employment. The company collects data about Internet performance and diagnostics. The data consists of millions of data points that need to be analyzed on an ongoing basis and the statistical implications of the measurement and interpretation techniques understood. Based on this analysis we will refine our measurement and analysis techniques, and be able to optimize the data collection.

Requirements are a BS in Mathematics or Statistics or equivalent and statistical data analysis experience. It would be desireable for the candidate to have :

practical experience in analyzing real-world data, experience in analyzing network data and in using databases and/or spreadsheets to analyze and visualize the data. Also desirable would be an MS in Statistics or equivalent and programming experience

Contact information:

Fax your resume to 408-486-6050 or email it to jobs@inversenet.com

We will contact you as soon as possible

May 1997

Joint Biostatistics and General Applications Program and Stanford Biostatistics Workshop

"Recent Developments in Survival Distribution"

Chin Long Chiang
University of California Berkeley, CA

Abstract

Two survival distributions will be proposed in this presentation. They are tentatively entitled: (1) Survival and stages of diseases, and (2) A yet unnamed distribution.

(1) Survival and stages of disease --- The development of many chronic conditions is characterized by stages. Generally, diseases advance with time from a primary condition through intermediate stages to advanced stages, to death. The process often is irreversible but a patient may die while being in any one of the stages. In the natural development of cancer, for example, there are stages of the disease determined by the and size of tumor and metastasis of cancer. AIDS also develops in stages. Explicit formulas will be presented for the density function, the distribution function, and moments of the distribution. Maximum-likelihood estimation of the parameters will be discussed.

(2) The yet unnamed distribution - There are two forces acting on a person to influence his survival and death. One force causes the force of mortality to increase, while the other force causes the force of mortality to decrease. A survival density function based on the interaction of the two forces will be proposed. Application of the distribution to the estimation of time to tumor will be presented.

Date: Wednesday, May 7, 1997

Time: 3:30 - 4:00 PM Coffee
4:00 - 5:00 PM Talk

Place: Room SU 1325, Cal State University, Hayward

Dinner for the speaker will follow at 6 PM

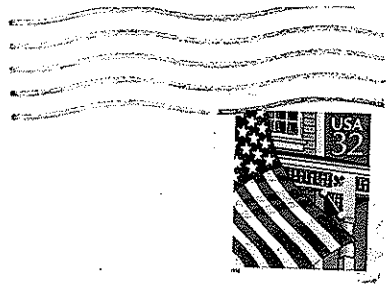
Cal State Hayward Directions:
From 880 north or south take the Jackson Ave. exit and head east (toward the hills).

From 92 East, continue over the 880 overpass.

Turn right onto Harder Road (first light after 880 overpass). Cross Mission Blvd. onto Cal State Hayward campus. SU appears shortly on the left. Lot C has metered areas. Day permits (6 quarters) are available at lots C and D near SU.

From 580/238, take the Hayward exit Foothill Blvd. Keep to the left at the sp the end of downtown Hayward, and go Mission Blvd. From Mission Blvd. turn either on Carlos Bee or on Harder Rd. C Bee ends on the Loop Rd. Turn right ont West Loop Road, then left onto Harder. are then near parking lot C and SU.

Visit our website at www.sfasa.



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