The American Statistical Association

San Francisco Bay Area Chapter

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January/February, 1997

Joint Biostatistics and General Applications Program

"Pharmacodynamic Analysis of Analgesic Clinical Trials: Statistical Solution"

Chui Yu Liu
Data Analysis Division
Department of Biopharmaceutical Sciences
University of California, San Francisco

Abstract

In the development of an analgesic product, placebo-controlled clinical trials in patients with defined pain are used to study the effect-dose-time relationship of the product. In such a trial, the response is usually an ordered categorical variable. The primary causal variables are time and analgesic concentration. The data are longitudinal and subject-specific with repeated measurement. During a treatment, if a subject has inadequate pain relief, he/she is remedicated with a known analgesic, and thus the responses may be right-hand censored. Logistic mixed effects models have been proposed to estimate the probability of having a certain category of response. If the baseline pain severity is of interest, conditional probabilities are also estimable. The response profiles of the subjects and the concentration-time information enable investigators to estimate missing responses. Posterior inference has been employed to validate the proposed method. Two examples are given to demonstrate the approach.

Date: Thursday, February 6, 1997

Time: 3:30 - 4:00 PM Refreshments
4:00 - 5:00 PM Discussion

Place: Chiron Corporation, 4560 Horton St., Emeryville

Dinner for the speaker will follow at 6 PM

Directions: Refer to enclosed map.

OPEN POSITIONS:

Senior Biostatistician

Clinical Company, Southern California

The minimum qualifications for this position are a M.S. in Biostatistics or a related field, or the equivalent combination of education and experience. The applicant will typically have five years of biostat/statistical clinical experience in the biotech/ pharmaceutical industry. The applicant must have good organization and planning skills. Good communication skills. Ability to effectively document activities and communications. Advanced understanding of clinical research methodology. FDA experience with good knowledge of FDA regulations. Experience with SAS, Windows and relational databases. Ability to accomplish tasks independently. Independent contribution to clinical study design and development.

If you are interested in this opportunity, please mail or Fax your CV/resume or contact: Anna Floyd; The Chase Group; Phone: 913-663-3100;

FAX: 913-663-3131;

e-mail: anna@chasegroup.com.

M.S. Biostatistician

Environmental Risk Analysis, San Mateo

Environmental Risk Analysis, Inc. is a new and rapidly growing scientific consulting firm that offers services in biostatistics, statistics, epidemiology and environmental risk analysis. Our clients

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are Fortune 500 companies and law firms. The position is located at our San Mateo office. We are seeking an individual with a Masters degree in Biostatistics or Statistics with courses or experience in environmental epidemiology.

Responsibilities of the position include:

- Performing statistical analyses using statistical software packages, primarily SAS;

- Performing critical reviews of health and medical literature related to epidemiology and environmental health;

- Assist in conducting quantitative health risk and statistical analyses;

- Writing computer code to perform specialized statistical analyses (SAS Macros, FORTRAN, S-Plus).

The ideal candidate will have course work or experience in linear models, categorical data analysis, survival analysis, epidemiologic methods, survey sampling, multivariate analysis and occupational and environmental health and epidemiology. Experience with IBM compatible PCs and using SAS on PCs is required. Experience with one programming language (FORTRAN, S-Plus) is desired. Good oral and written communication skills are necessary.

For confidential consideration please send a resume to:

William Butler, Ph.D.

Environmental Risk Analysis, Inc.

1670 Amphlett Blvd., Suite #115

San Mateo, CA 94402-2512

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are Fortune 500 companies and law firms. The position is located at our San Mateo office. We are seeking an individual with a Doctorate degree in Biostatistics or Statistics with 3+ years of experience including quantitative health risk analysis.

Responsibilities of the position include:

- Performing critical reviews of health and medical literature related to epidemiology and environmental health;

- Communication (written and oral) of findings and conclusions to team members, clients and health professionals;

- Performing and supervising statistical analyses of health and environmental data sets using statistical software packages, primarily SAS and SUDAAN;

- Assist in conducting quantitative health risk and statistical analyses.

The ideal candidate will have experience and/or course work in occupational and environmental epidemiology, quantitative risk assessment, research design; and statistical methods including linear models, categorical data analysis, survival analysis, survey sampling and multivariate analysis. Demonstrated ability to communicate technical information is required as is experience with IBM compatible PCs and SAS. Experience with one programming language (FORTRAN, S-Plus) is desired.

For confidential consideration please send a resume to:

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San Mateo, CA 94402-2512

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Senior Statistical Analyst

Technology Assessment Group, San Francisco

Technology Assessment Group (TAG) is a San Francisco-based international health care research and consulting firm with special expertise in the evaluation of economic and quality-of-life impacts of new medical technologies and health conditions.

We seek 1-2 individuals with 5 years of experience performing data analysis in a research environment. The ideal candidate has a MS or Ph.D. in statistics, 5 to 10 yrs of experience performing statistical analysis using SAS software and 2 to 3 years of experience supervising SAS data analysts. This position requires a thorough understanding of SAS data step programming and statistical analysis procedures, especially linear models. Experience analyzing survey data, processing medical claims data, and working with large data sets are desirable. Excellent written and verbal communication skills and an ability to explain sophisticated statistical methods to non-specialists is essential.

Please supply salary requirements. TAG offers competitive salaries & benefits.

Please send resume and cover letter to:

Technology Assessment Group

490 Second Street

Suite 201

San Francisco, CA 94107

Fax: 415/904-4158

e-mail: ceubanks@tagsf.com .

No calls. EOE.

Statistical Research Consultant

Kaiser Permanente, Oakland

The Special Studies department of Kaiser Permanente's Program Offices is seeking a statistical research consultant. This FTE position requires at least a Master's degree with an emphasis on quantitative studies and three or more years of research, preferably in health care.

Applicants must demonstrate knowledge of multivariate and distributional statistical methods, proficiency in SAS programming and familiarity with technical consulting. Studies apply epidemiologic and statistical methods to analyses of large, complex computerized data sets. Current topics include assessment of health outcomes,

development of risk adjustment techniques and analysis of health services utilization.

Send CV to:

Director of Special Studies

Kaiser Permanente

One Kaiser Plaza

Oakland CA 94612

Fax: 510-271-5815.

Master's Level Statistician

Financial Proformas, Inc.

Walnut Creek

Master's level professional statistician, ideally with experience in building credit scoring models, to serve as a deputy statistician in a multi-year project for a Bay Area financial analysis software and credit training company. Please send information to:

Financial Proformas, Inc.

1350 Treat Boulevard

Suite 400

Walnut Creek, California 94596

Attention: Rex Beach

Sr. Statistical Programmer Analyst

Corning Besselaar

Key Responsibilities

- •Perform as a key resource in a technical area or in project management
- •Analyze and improve departmental processes
- •Perform as a key SAS programmer for development and projection projects.
- •Review and interpret Report and Analysis Plans for assigned projects.
- •Lead programming efforts for (CA)NDS/(CA)PLA preparation.
- Review draft and final production runs for any project.
- •Complete assigned tasks in an accurate and timely manner, while following Statistical Programming Standard Operating Procedures.
- •Assist with interviewing potential candidates.
- •Assist with time and cost modifications on assigned projects and estimates on proposals.
- •Perform other duties as assigned by management.

Qualifications

Education

B.S. or equivalent in computer science or related field.

Experience

Required

- •Minimum 5 years.
- •Expert understanding of SAS.
- •Minimum 5 years of complex SAS programming experience.

Preferred

- Thorough understanding of Besselaar Statistical Programming procedures.
- Two years programming experience at Corning Besselaar.

Special Skills

Required

- Excellent written and oral communication skills.
- Good understanding of overall clinical research development process.
- Project management or system development experience is beneficial.
- Interact with Project Core Team Members.
- Assign and monitor work of the programming team working on assigned projects.
- Client contact on project specific and technical issues.
- Overtime required occasionally.
- Attend client meetings to discuss project related issues.
- Possible travel for client meetings.
- Flexibility to modify plans and resources to meet Project Team and client goals.
- Ability to plan and organize work of a programming team.
- Ability to make decisions to accomplish team goals.

If you are interested, please submit your resume to:

Human Resources Manager

Corning Besselaar, Inc.

200 Pringle Ave., Ste. 555

Walnut Creek, CA 94596

Fax: (510)974-3703

Senior Project Statistician

Corning Besselaar

Walnut Creek

Key Responsibilities

- Serve as core project team member to coordinate and manage all statistical activities on a project and provide statistical liaison with client.
- May serve as project director.
- Provide statistical input for protocol and CRF development.
- Prepare RAPs (detailed specifications for the format and content of clinical trial reports, including table of contents, description of study design, definition of efficacy and safety variables, data handling conventions, methods of statistical analysis, programming rules, mock-ups for tables and listings).
- Provide direction to programmers and data associates during production and review of computer generated tables and listings for CTR.
- Review computer-generated tables to verify accuracy.
- Prepare key portions of integrated clinical/statistical report, including sections related to data handling and statistical methodology, patient accountability, baseline compatibility and efficacy results.

- Prepare key sections of the ISS and ISE, including those related to data-handling and statistical methodology, patient accountability, baseline compatibility and efficacy results.
- Perform other duties as assigned by management.

Qualifications

Educational

Required

M.S. in Statistics

Preferred

Ph.D. in Statistics

Experience

Required

Minimum 2 years as Statistician

Preferred

Minimum 3 years as Statistician in Pharmaceutical Setting.

Special Skills

- Good written and oral communications skills.
- Computer proficiency in Word Processing and SAS programming.

If you are interested, please submit your resume to:

Human Resources Manager

Corning Besselaar, Inc.

200 Pringle Ave., Ste. 555

Walnut Creek, CA 94596

Fax: (510)974-3703

Senior Data Associate
Corning Besselaar
Walnut Creek

Key Responsibilities

- Key project team member with responsibility for maintenance of clinical database
- Data Associate's responsibilities, plus the following:
- Develop time and cost estimates
- Participate in proposal activities and client presentations.
- Participate in development of Case Report Forms.
- Mentor, train and supervise staff performing data management and data entry.
- Manage data clean-up process.
- Perform other duties as assigned by management.

Qualifications

Educational

Required

BA/BS

Experience

Required

Minimum 4 years increasing responsibility in data management of clinical trials.

Special Skills

Required

- Computer literacy.
- Good verbal and oral communication skills.
- Ability to work independently
- Time Management.
- Ability to supervise staff.

If you are interested, please submit your resume to:

Human Resources Manager

Corning Besselaar, Inc.

200 Pringle Ave., Ste. 555

Walnut Creek, CA 94596

Fax: (510)974-3703

Statistical Programmer
Corning Besselaar
Walnut Creek

Key Responsibilities

- Modify, validate, and implement project work in SAS primarily utilizing existing code.
- Supervision is expected.
- Assemble and validate production table runs.
- Modify and maintain existing programs and writing new SAS code to produce diagnostics for data review.
- Modify and maintain programs and writing simple SAS code with programming team support to produce data listings, summary tables, and graphs as specified in the Report and Analysis Plans.
- Create programs for routine data transfers.
- Assist with programming for tables for DSMB review and periodic interim analyses.
- Completing assigned tasks in an accurate and timely manner, while following Statistical Programming Standard Operating Procedures.
- Perform other duties as assigned by management.

Qualifications

Educational

Required

A.A.S.

Preferred

B.S. preferred in computer science or related field.

Special Skills

Required

- Good programming skills.
- Basic understanding of Base SAS
- Ability to make use of and modify existing SAS code.
- Interact with other programmers and Statistical Programming project managers.
- Discuss requests with statisticians, project associates, and data associates.
- Overtime required occasionally.
- Ability to communicate effectively verbally.
- Ability to follow directions.
- Ability and desire to quickly learn new job-related information and to increase independence.
- Willing to modify plans and behavior when necessary to meet a goal.
- Ability to shift priorities according to project tasks and requirements.

Preferred

- Exposure to SAS/STAT and macro language.

If you are interested, please submit your resume to:

Human Resources Manager

Corning Besselaar, Inc.

200 Pringle Ave., Ste. 555

Walnut Creek, CA 94596

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Biostatistician

SEQUUS

Menlo Park

SEQUUS Pharmaceuticals, Inc. is a leader in the development, manufacture, and commercialization of liposomal drugs and lipid-based biopharmaceutical products primarily to treat cancer and infectious diseases. Proud to be among the 2 percent of biotech companies formed in the last 20 years with approved products on the U.S. market, we are building our talented team further success.

The successful candidate should have a Ph.D. or M.S. in Biostatistics or Statistics with substantial experience in protocol development, analysis, conduct of multi-center clinical trials (experience in cancer clinical trials is a plus), and experience in NDA submissions. Knowledge of FDA regulations and regulatory submission process is required. Excellent communication, organizational, planning and documentation skills are essential. Broad knowledge of statistical methods for the analysis of clinical trials (Phase I through IV) is required.

To achieve SEQUUS's mission of improving patients' lives, we are building teams and empowering the best talent in our industry, providing a productive professional environment, and rewarding performance linked to the achievement of goals. Please send your resume to:

SEQUUS Pharmaceuticals, Inc.

Professional Staffing

0 Hamilton Court

Menlo Park, CA 94025

fax (415)453-3124.

We promote a diverse workforce/EOE.

Statistician

Bank of America

San Francisco

Bank of America is seeking statisticians for its retail banking marketing group in San Francisco. You will be responsible for the development and implementation of statistical models to improve sales and marketing programs in retail banking. The statistical models you will develop will predict attrition, product and response propensity to specific products and promotions using current customer data.

The ideal candidate will have a MS in Statistics plus at least 2 years related business experience. Expert with SAS and experience using large data sets. SQL a plus. Strong project management and communication skills are essential.

E-mail your resume to: Henry.Bennett@Bankamerica.com

or mail your resume to:

Henry Bennett

San Francisco Recruiting Resources #13608

SFASA-HB8444

P.O. Box 37000

San Francisco, CA 94137.

Senior Statistician

Financial Proformas Inc.

Walnut Creek

Financial Proformas Inc. was founded in 1981 and currently has a full-time employed staff of approximately 70. FPI is the market leader in providing P.C. and server based software work tools to commercial bank lenders to assist them in evaluating and processing commercial loan trans-actions. The Company's principal software products are installed in more than 50 of the top 100 banks in the U.S. and a total of more than 2000 institutions world-wide. Staffed by bankers, financial specialists, software development professionals and training experts, FPI uses proven expertise in applying the science of computing technology and credit management to the art of risk assessment and management of the commercial lending process. FPI sells its software products and education services directly to its user-clients through a network of full-time sales people resident throughout the U.S. as well as in Canada, Australia, and the U.K. FPI is available in English, French Canadian, Spanish Danish, German and Dutch. Credit educational materials are available using U.S., Canadian, Australian, and U.K. terminologies and formats.

The Senior Statistician will assume immediate managerial responsibility for a body of on-going developmental work in building and testing large scale computer based models which provide predictive outcome estimates based on large samples (60,000) of commercial loan and related financial data. The end product of the work can be viewed as the commercial loan equivalent of consumer loan credit scoring technology. Clients of the Company will use the results of this work to improve their ability to assess individual, and consequently, loan portfolio risk levels, shifts in those levels and as an input to adjusting loan policy.

Success in this position requires substantial knowledge and proven skills in a wide range of disciplines, including

- Demonstrated successes in building/utilizing statistical models to predict likely outcomes.
- Knowledge of commercial financial analysis; experience in commercial loan processing systems would be a significant plus

Ph.D. or MA degrees in mathematics, statistics, or operations research.

If you have interest, please Fax your resume and any other pertinent information to:

Paul Erickson

Strategic Consulting Services

Fax:(415)435-0376.

Chapter Announcement

The San Francisco Chapter of the American Statistical Association has begun sponsoring an electronic mailing list to disseminate meeting notices, job openings, and other announcements of interest to chapter members.

To subscribe to the list, send an e-mail message to

sfasa-request@lists.best.com

The body of the message should contain only one line:

subscribe

On receipt of your message, the mailing list manager will add your return address to the subscription list. If you would like to add an address other than your return address, or if you want to subscribe a third party to the list, then an optional e-mail address should be appended to the message, for example, *subscribe myname@aol.com*

Chapter members are also encouraged to contribute their own communications for distribution to other list subscribers. Subscribers can post announcements simply by sending them to **sfasa@lists.best.com**

The list is moderated meaning that messages are reviewed by a Chapter officer before being posted. There are no firm restrictions on content other than that electronic junk mail or "spam" is prohibited and will not be posted.

To remove your name from the mailing list after you've subscribed, send a message to

sfasa-request@lists.best.com

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unsubscribe

An optional e-mail address can be added after the keyword "unsubscribe" to remove a third party from the list. To obtain an automatically generated help file, send a message to **sfasa-request@lists.best.com**

containing the single keyword "help," or for a personal response, write to **sfasa-owner@lists.best.com**

Moving? Make sure we have your current address!

Each month we receive several newsletter returns because the post office time limit for forwarding mail has lapsed. Sometimes the forwarding address is included by the post office, but sometimes it is not.

Please make sure you don't miss a newsletter. Contact Ann Kalinowski, the chapter secretary, with your new address. Phone (415)688-7203, or e-mail sfamk@fail.com.

Newsletter Submissions

The chapter newsletter runs employment ads free of charge as a service to its subscribers. Other advertisements are placed in the newsletter for a nominal charge to cover the additional copying and postage costs.

Other submissions (anecdotes, public seminar notices, jokes, etc.) are also placed free of charge. Any contributions are welcome. Send them to Ann Kalinowski, Failure Analysis Associates, 149 Commonwealth Dr., Menlo Park, CA 94025. Phone: (415) 688-7203, fax: (415) 238-2988, e-mail: sfamk @fail.com.

Directions to Chiron:

From SFO/Peninsula:

Take the Bay Bridge to 80N towards Berkeley. When on 80, immediately move to the right and exit on **Powell**.

Turn **RIGHT** at the bottom of the offramp (signal). Go through the next signal (on Christie), over the Amtrack bridge and turn **RIGHT** at the next signal (Hollis). Proceed to 53rd street (next signal intersection) and turn **RIGHT**. Go 1/2 block down and turn **LEFT** into the Chiron parking lot. Enter through the glass front that looks somewhat like a wine barrel. The conference room is immediately inside on the right. The receptionist can direct you.

From Berkeley:

Take University west to the bay frontage road (just past (and parallel to) I80. Turn **LEFT** and go to **Powell**. Turn **LEFT** onto Powell and follow directions from SFO above.

From East Bay: Take appropriate freeway (24W to 580 to 80N or 880 to 580 to 80N) to arrive at **Powell** offramp on 80N and follow directions from SFO above.

Note: When you arrive at Chiron, it is likely that the parking lot will be full owing to ongoing construction. If this is the case, you should either a) park on Hollis or b) park in the lot located just off of Hollis and Powell. It is suggested that you plan to arrive early in anticipation of parking difficulties.

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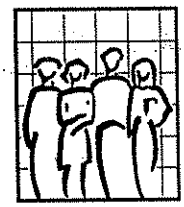

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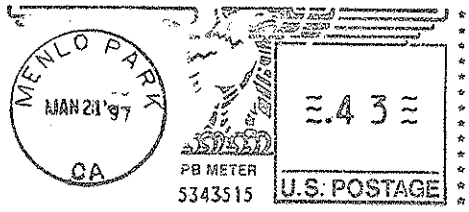

San Francisco Bay Area Chapter

American Statistical Association

149 Commonwealth Drive

Menlo Park CA 94025

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