

CURRICULUM VITAE

Susan E. Spruill

STATISTICAL CONSULTANT

APPLIED STATISTICS AND CONSULTING, SPRUCE PINE, NC

President and Owner

January 20, 2006 – Present

Provides statistics related support to clients in the pharmaceutical industry, crop, animal and environmental sciences, and the social sciences. Support includes assistance with development of product development plans, experimental design, sample size calculations, randomizations schemes, assistance with grant writing, protocol writing, report or manuscript writing. Actual statistical analyses are limited to exploratory analyses, small scale statistical analyses (i.e., hypothesis testing) and validation of results produced by others using the latest version of PC SAS. Large scale SAS programming for production of tables and listings for regulatory submissions are outsourced and managed.

POZEN, INC., CHAPEL HILL, NC

Senior Director of Biostatistics

November 1, 2001 – September 8, 2006

Responsible for assuring that the experimental design, statistical analyses and reporting of all clinical studies performed by POZEN meet accepted statistical and regulatory standards. Provide statistical expertise and guidance to Product Development personnel; provide review of statistical work (e.g., statistical tables) completed by internal/external statistical personnel. Specific duties include: providing statistical support for exploratory analysis of data, and power calculations; providing statistical expertise in areas that include experimental design, statistical methodology, and regulatory reporting requirements; facilitating the development of POZEN's data management systems in accordance with current corporate needs; providing timely communication of corporate initiatives and priorities to all Product Development members; providing input to the corporate business plan and strategic initiatives; maintaining policies and procedures (e.g., SOP's and Working Practices) and ensure compliance, and assuring adherence to good scientific, ethical, and regulatory standards.

DNA SCIENCES LABORATORIES (FORMERLY PPGX, INC.) MORRISVILLE, NCExecutive Director, Statistical Genomics

June 1, 2000 – September 18, 2001

Responsible for providing statistical support services to various components of PPGx's management. Duties include, evaluation and consultation on the variability of laboratory techniques based on statistical modeling and analyses, development and maintenance of alliances with various universities, providing consultation in bridging research between genomics and clinical trials, evaluating and collaborating in sample acquisitions, and providing statistical support in research initiatives, software development and clinical collaborations involving genetic associations to clinical outcome.

PPD DEVELOPMENT, MORRISVILLE, NCExecutive Director, Biostatistics

1994 – May 31, 2000

Responsible for management of 75+ staff of data managers, programmers and biostatisticians in providing statistical support services to clients conducting all phases of clinical trials. Duties include providing statistical consulting expertise to sponsors, providing FDA submission support to sponsors, developing and reviewing protocols, coordinating and supporting a team of data managers and biostatisticians in developing databases, developing and deploying remote data entry systems, developing analysis plans which include listings and summary tables specifications, providing statistical support to medical writers, and designing randomization schedules. Major areas of support include Phase I trials utilizing pharmacokinetic parameters for determination of bioavailability/bioequivalence, full clinical development programs, coordination and support of international clinical trials, integrated summaries of safety and efficacy, and support for regulatory submissions of BLAs, NDAs, sNDAs, aNDAs and CANDAs.

THE CADMUS GROUP, INC. DURHAM, NCAssociate Statistician:

1992-1994

Provided statistical analytical support to the Acid Rain Division of the EPA during the development of rules for amendments of the 1990 Clean Air Act. Responsibilities included statistical research and analyses pertaining to continuous emissions monitoring systems; investigations of consistency in Relative Accuracy Test Audits (RATAs); variance component analyses of collaborative laboratory RATAs for qualifying laboratory reproducibility; and

effects of autocorrelation on estimations of precision, relative accuracy, and reliability of alternative monitoring systems.

**NORTH CAROLINA STATE UNIVERSITY, DEPARTMENT OF STATISTICS,
RALEIGH, NC**

Statistical Consultant to the USDA Forest Service

1984-1992

Acted as project manager for the statistical consulting division of the Southern Commercial Forest Research Cooperative and the Southern Global Change Program. Duties included developing experimental designs for studies that examined the effects of increasing ozone levels and acidic rain on commercially important pine species. Directed the combined synthesis and integration of 3 years of data collected by cooperative researchers at universities in North Carolina, South Carolina, Florida, Alabama and Texas.

Assistant Statistician to the USDA Agriculture Research Service

Assisted in the combined analysis of the effects of ozone, SO₂ and moisture stress on commercially important crops for the development of an integrated database for the national Crop Loss Assessment Network.

EDUCATION

- North Carolina State University, Raleigh, NC
MS, Quantitative Genetics (minor Statistics and Reproductive Physiology)
1984
- North Carolina State University, Raleigh, NC
BS, Zoology
1982