

# MARLISA ELIZABETH ANDERSON, MPH

619-791-4244

marlisa@copperrockresearch.com

---

## SUMMARY

Senior statistician with over 28 years of experience in biotechnology. Strengths include hands-on planning and execution of statistical analyses for phase 1 through 3 clinical studies. Strategic operational biostatistics team member who primarily works with small biotechnology companies across a range of therapeutic indications but with a heavy concentration in oncology. Strengths include:

- Writing Statistical Analysis Plans
- Writing and reviewing Clinical Study Reports
- Working with laboratory and vendor data
- Reviewing tables, figures, and listings
- Managing Contract Research Organizations
- SAS programming
- Sample size calculations
- Randomization schedules
- Interim analyses
- Adaptive designs
- Creating table, figure, and listing reporting shells
- FIH Dose escalation study design

## PROFESSIONAL EXPERIENCE

### **COPPER ROCK RESEARCH, INC., San Diego, CA**

**2006 – Present**

#### *President*

Founded corporate consulting firm to provide statistical consulting services to the biotechnology community. Currently working with clients on a wide range of studies ranging from phase 1 safety to phase 3 efficacy studies with emphasis in oncology over the last 16 years. Have also worked on phase 1 safety and dose escalation studies, including pharmacokinetic and pharmacodynamic studies, QTc cardiac safety studies, hepatic impairment, and food-effects studies, as well as phase 2 efficacy and proof of concept studies. Tasks include working with multidisciplinary teams to design and write clinical study protocols, writing and approving statistical analysis plans, reviewing data, programming analyses in SAS, providing quality review of tables, figures and listings, writing statistical sections of Clinical Study Reports, Investigator's Brochure's, and Annual Reports to the FDA, and preparing data for journal publications.

### **NEUROCRINE BIOSCIENCES, INC., San Diego, CA**

**2001 – 2006**

#### *Senior Biostatistician*

**2005 – 2006**

In addition to the responsibilities described below as Biostatistician, served as Lead Statistician for Phase I and II studies.

- Performed statistical modeling of clinical pharmacokinetic and pharmacodynamic data.
- Wrote and approved statistical analysis plans.
- Corresponded with the FDA in response to questions regarding a New Drug Application.
- Guided in-house statistical programmers in the production and quality review of tables, listings and graphs.
- Disease indications included insomnia and endometriosis.

#### *Biostatistician*

**2002 – 2005**

Responsible for review of statistical analysis plans, clinical study reports, protocols, data management plans, data export agreements, database setup, and case report forms. Managed relationships with contract research organizations.

- Managed statistical and data management work outsourced to Contract Research Organizations for multiple phase 2 and 3 studies.
- Reviewed clinical data from multiple phase 2 and 3 studies for accuracy and completeness.
- Oversaw an interim analysis including selection of data monitoring committee members, evaluation of analysis methods, and analysis plans.
- Presented results of clinical studies to project teams.
- Planned the data integration and reviewed clinical summaries of safety and efficacy in support of two New Drug Applications.
- Performed exploratory ad hoc statistical analyses of clinical data from phase 1-3 studies.
- Led the validation of the installation of SAS software. Wrote the validation master plan, installation qualification protocol, and operational qualification protocol, interviewed validation contractors, evaluated proposals, and determined hardware and software requirements.
- Led the development of core standard operating procedures (SOPs) for statistical programming and biostatistics functions. Wrote all SOPs, led group reviews, and trained department members on approved SOPs.

**HOLLIS-EDEN PHARMACEUTICALS, INC., San Diego, CA****2001 – 2002***Associate Biostatistician*

Responsible for performing analyses on clinical and pre-clinical data within all program areas of the company. Included writing and editing of statistical analysis plans, performing sample size calculations, and reviewing clinical data and SAS programs for quality assurance.

- Consulted with scientific and clinical staff on study design.
- Performed interim analyses of Phase I/II clinical trials.
- Developed standard SAS programs to create derived datasets.
- Created standard tables for clinical study reports.
- Disease indications included HIV, malaria, lipid metabolism, and autoimmune diseases.

**THE IMMUNE RESPONSE CORPORATION, San Diego, CA****1998 – 2001***Biostatistician***1999 – 2001**

In addition to the functions of the Clinical Programmer Analyst listed below, responsibilities also included writing statistical analysis plans and statistical sections of clinical study reports. Served as project lead for all HIV, rheumatoid arthritis, and multiple sclerosis studies. Supervised and trained Clinical Data Management staff.

- Created randomization schedules.
- Worked with corporate partners on the design and analysis of clinical trials.
- Consulted with investigators on the analysis of investigator-IND trials.
- Worked with CROs on outsourced trials.
- Disease indications included HIV, rheumatoid arthritis, multiple sclerosis, and psoriasis.

*Clinical Programmer Analyst***1998 – 1999**

Provided SAS Programming and analysis for all phases of clinical and pre-clinical development. Produced standard tables and listings to support IND safety submissions and clinical study reports.

- Conducted statistical analyses in support of journal publications and product development.
- Communicated results of analyses to scientific and clinical staff.

**SAN DIEGO COUNTY EMERGENCY MEDICAL SERVICES, San Diego, CA****1997 – 1998***Biostatistician*

Managed databases, computed statistics on injury and disease for data requests and research projects, and provided statistical consulting for clinical studies.

**SAN DIEGO STATE UNIVERSITY FOUNDATION, San Diego, CA** **1996 to 1997**

***Program Evaluation Specialist***

Contractor to San Diego County Infant Immunization Initiative

Designed methods to evaluate health promotion and assessment activities. Created surveys, databases, spreadsheets, information tracking protocols, and computed statistics. Compiled and communicated results of studies and surveys.

**THE COLUMBUS HEALTH DEPARTMENT, Columbus, OH** **1996 – 1996**

***Epidemiologist***

Assessed the health of the community by calculating, compiling, and reporting morbidity and mortality statistics for the City of Columbus and Franklin County.

**MANAGEMENT ASSISTANCE CONCEPTS CORPORATION, San Diego, CA** **1995 – 1996**

***Epidemiologist II***

Contractor to Naval Health Research Center, Medical Information Systems Department

Designed a field medical surveillance system to provide field epidemiologists with an electronic means of disease surveillance.

**SAN DIEGO STATE UNIVERSITY FOUNDATION, San Diego, CA** **1994 – 1995**

***Student Research Analyst***

Contractor to Naval Health Research Center, Department of Clinical Epidemiology.

Developed risk profiles using logistic regression modeling techniques to identify US Navy SEAL trainees most at risk for overuse injury.

**GEO CENTERS, INC., San Diego, CA** **1991 – 1994**

***Scientist I***

Contractor to Naval Health Research Center, Department of Operations Research.

Conducted research on previous military engagements to predict future casualty, illness, and injury rates for medical planning purposes.

## EDUCATION

Master of Public Health, Epidemiology & Biostatistics, San Diego State University 1995

Bachelor of Arts, Psychology, University of California at San Diego 1991

## RELEVANT VOLUNTEER EXPERIENCE

**SAN DIEGO HOSPICE AND PALLIATIVE CARE, San Diego, CA** **2006-2007**

***Member, Institutional Review Board***

Performing statistical review and approval of all patient research proposals and protocols submitted to the Institutional Review Board (IRB). Engaging in open discussion during IRB meetings regarding

proposed research methods, data collection, data privacy issues, data analysis, informed consent, and patient safety.

**GREATER SAN DIEGO SCIENCE & ENGINEERING FAIR, San Diego, CA**      **1999 – 2003**

***Judge***

Judged middle and high school student science projects in a variety of categories.

**PUBLICATIONS**

1. Sandip Patel MD, Manish Patel DO, Martin Gutierrez, Marlisa Anderson, Peter Szabo, Bob Valamehr, Yu-Way Chu, Brandon Beagle, Jeffrey Chou, David Hong. Results of a Phase 1 trial of FT500, a first-in-class, off-the-shelf, iPSC-derived NK cell therapy combined with PD-1/PD-L1 checkpoint blockade therapy and IL-2 in patients. Published at SITC 2022.
2. Krish Patel, Veronika Bachanova, Aaron M Goodman, John M Pagel, Kelly Griffis, Marlisa Anderson, Siminder Atwal, Cara Bickers, Peter Szabo, Lilly Wong, Yu-Way Chu, Rebecca Elstrom, Paolo Strati. Phase 1 study of FT516, and off-the-shelf iPSC-derived NK cell therapy, in combination with Rituximab in Patients with Relapsed/Refractory B-Cell Lymphoma. Published at ASH 2021.
3. Paolo Strati, Veronika Bachanova, Aaron Goodman, John M Pagel, Januario E Castro, Kelly Griffis, Marlisa Anderson, Siminder K Atwal, Cara Bickers, Daniel Fremgen, Christina Ly, Sarah A Cooley, Rebecca L Elstrom, Krish Patel. Preliminary results of a phase 1 trial of FT516, an off-the-shelf natural killer (NK) cell therapy derived from a clonal master induced pluripotent stem cell (iPSC) line expressing high-affinity, non-cleavable CD16 (hnCD16). Published at ASCO 2021.
4. Sandip Patel MD, Manish Patel DO, Kimberly Musni BSHA, Marlisa Anderson MPH, Sarah Cooley MD, Bahram Valamehr PhD, Yu-Way Chu MD and David Hong. Preliminary results of an ongoing phase 1 trial of FT500, a first-in-class, off-the-shelf, induced pluripotent stem cell (iPSC) derived natural killer (NK) cell therapy in advanced solid tumors. Published at SITC 2020.
5. Joleen Marie Hubbard, Manish R Patel, Tanios S Bekaii-Saab, Gerald Steven Falchook, Bradley L Freilich, Arvind Dasari, Benjamin T Knisely, Marlisa Anderson, Gary Gene Chiang, Kevin R Webster, Sam Sperry, Jeremy Barton, Johanna C Bendell. A Phase II open label, randomized, noncomparative study of eFT508 (tomivosertib) alone or in combination with avelumab in subjects with relapsed/refractory microsatellite stable colorectal cancer (MSS CRC). Published at ASCO 2019.
6. San Diego County Prehospital Annual Report. County of San Diego, Department of Health Services. (San Diego: September 1997). This report discusses the San Diego County Emergency Medical System and presents system responsiveness and patient demographics collected from ambulance runs.
7. The City of Columbus Mortality Report. The Columbus Health Department. (Columbus: April 1996). This report presents statistics on the leading causes of death in the City of Columbus.
8. Anderson, Marlisa Elizabeth, (1995). The association between lower extremity range of motion measurements and incidence of stress fracture among US Navy SEAL trainees. SDSU Thesis (Public Health).
9. Blood, C.G., Anderson, M.E., and Gauker, E.D. (1993). Casualty rates among Naval forces ashore. *Military Medicine*, 158 (12), 774-777.
10. Blood, C.G., Anderson, M.E. (1994). The battle for Hue: casualty and disease rates during urban warfare. *Military Medicine*, 159 (9), 590-595.

**PRESENTATIONS**

1. "Restraint use in children under the age of 5 involved in motor vehicle crashes; demographics and injuries." Preventing Childhood and Adolescent Injuries: Eleventh Annual California Conference. San Diego, CA (October, 1997).
2. "Injury patterns among youth under age 25 in San Diego County." Preventing Childhood and Adolescent Injuries: Eleventh Annual California Conference. San Diego, CA (October, 1997).
3. "A descriptive analysis of patient data by restraint status for motor vehicle crashes." American Public Health Association 125th Annual Meeting. Indianapolis, IN (November, 1997).
4. "Association of Lower Extremity Range of Motion Measurements and the Incidence of Stress Fracture among US Navy SEAL Trainees." American Public Health Association 123rd Annual Meeting. San Diego, CA (October, 1995).

### CONTINUING EDUCATION

- 2<sup>nd</sup> Annual Basket, Umbrella and Platform Trials Conference, Philadelphia PA. October 2019. 16 hours.
- 2012 Joint Statistical Meetings of the American Statistical Association, San Diego, CA. 32 hours.
- 2006 Annual Workshop on Statistical Methodologies in the Biopharmaceutical Sciences, Washington, DC. March 2006. 24 hours.
- 2005 FDA/Industry Statistics Workshop, Washington, DC. September 2005. 24 hours.
- Pharmaceutical Industry SAS Users Group Conference, San Diego, CA. May, 2004. 40 hours.
- SAS Programming for the Pharmaceutical Industry, pre-conference seminar, May 2004. 4 hours.
- Building and Applying Predictive Models Using the SAS System. Sierra Information services, Inc. San Diego, CA. April 2002. 8 hours.
- Good Clinical Practices. Quality Assurance Systems, Inc. San Diego, CA. Mar/April 2002. 16 hours.
- SAS SQL Programming Tips. Software Intelligence Corporation. San Diego, CA. April, 2001. 4 hours.
- West Coast Data Management and Biostatistics: A Focus on Emerging Companies. 4th Annual DIA Sponsored Workshop. San Francisco, CA. December, 2000. 16 hours.
- Western Users of SAS Software. 8th Annual Conference, Scottsdale, AZ. September, 2000. 24 hours.
- New Features in Version 8 of the SAS System. SAS Institute, Inc. Irvine, CA. January, 2000. 16 hours.
- Pharmaceutical Industry SAS Users Group Conference, New Orleans, Louisiana. May, 1999. 40 hours.
- SAS Macro Language. SAS Institute Inc., Irvine, CA. March, 1999. 16 hours.
- SAS Programming. SAS Institute Inc., Irvine, CA. June, 1998. 24 hours.
- Introduction to Solaris UNIX. Copernicus Computer Services Corporation, Carlsbad, CA. April, 1998. 16 hours.
- The Drug Development Process. University of California at San Diego, Extension, San Diego, CA. January to March, 1998. 30 hours.
- Communicating Public Health. American Public Health Association 125th Annual Meeting and Exhibition, Indianapolis, IN. November, 1997. 40 hours.
- Preventing Child and Adolescent Injuries: Eleventh Annual California Conference, San Diego, CA. October, 1997. 32 hours.
- Medical/Clinical Terminology. University of California at San Diego, Extension, San Diego, CA. July, 1997. 8 hours.

- Institutional Review Boards and Human Subjects Protection. University of California at San Diego, Extension, San Diego, CA. October, 1997. 8 hours.
- Good Clinical Practices. University of California at San Diego, Extension, San Diego, CA. September to November, 1997. 30 hours.
- Getting Started in Injury Control and Violence Prevention; an interactive satellite video conference. UNC Injury Prevention Research Center and Centers for Disease Control and Prevention, San Diego, CA. June, 1997. 8 hours
- Shaping EMS for the 21st Century. Emergency Medical Services Administrators' Association of California (EMSAAC) 1997 Annual Conference, San Diego, CA. May, 1997. 24 hours.
- Empowering the Disadvantaged: Social Justice in Public Health. American Public Health Association 124th Annual Meeting and Exhibition, New York, NY. November, 1996. 40 hours.
- Decision Making in Public Health: Priorities, Power, and Ethics. American Public Health Association 123rd Annual Meeting and Exhibition, San Diego, CA. October, 1995. 40 hours.