SIMON P. WEISENHORN

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EDUCATION

North Carolina State University - Raleigh, NC

August 2023

Master of Statistics

- GPA: 3.567
- Relevant Coursework: Statistical Principles of Clinical Trials, Applied Multivariate and Longitudinal Data Analysis, Statistical Programming, Advanced Statistical Programming, Fundamentals of Statistical Theory I, Fundamentals of Statistical Theory II, Applied Statistical Methods, Fundamentals of Linear Models and Regression, Data Science for Statisticians, and Statistical Practice

University of North Carolina at Chapel Hill - Chapel Hill, NC

May 2022

B.S., Statistics and Analytics

Data Science Minor

- GPA: 3.485
- Relevant Coursework: Advanced Methods of Data Analysis, Data Science, Stochastic Modeling, Probability, Optimization, Linear Algebra, and Multiple Variable Calculus

EXPERIENCE

Ora, Inc. – Raleigh, NC

September 2023 – Present

Biostatistician; Contract research organization specializing in full-service ophthalmology

- Write statistical analysis plans ensuring appropriate regulatory requirements and study objectives defined in the study protocol are followed.
- Lead several early phase studies ranging from dry eye disease to retinitis pigmentosa comprised of a large team based in Hyderabad, India.
- Develop TLF shell documents for programmers to reference.
- Review CRFs to ensure consistency with protocol and adequacy in collecting data to meet objectives and statistical analyses defined in the protocol.
- Develop SDTM (Study Data Tabulation Model) and ADaM (Analysis Dataset Model) mapping documents and datasets.
- Program summary tables, data listings and graphical representations of clinical trials data.
- Ensure proper execution of all analyses defined in the statistical analysis plan as well as any post-hoc analyses and relevant exploratory analyses of clinical trial data.
- Perform statistical QC of final clinical study reports by reprogramming important pieces of the programmed output.
- Contribute to the development of standard operating procedures for clinical trials.
- Represent Statistical Operations Department at regulatory meetings, sponsor meetings, and any other multifunctional meetings, as needed.
- Manage biostatistics timelines, budgets, and client expectations.
- Adhere to all essential systems and processes that are required at Ora to maintain compliance to Ora's data integrity & business ethics and regulatory requirements.

Catalyst Clinical Research – Raleigh, NC

May 2020 – August 2022

Biostatistician Intern; Contract research organization providing multi-therapeutic resourcing and cancer therapies

- Assisted lead project statistician in several different early phase clinical trials ranging from standard oncology studies to more unique studies, such as ones dealing with Achondroplasia.
- Validated study listings using SAS version 9.4 on a Windows based platform
- Reprogrammed listings for an independent validation
- Annotated all of the case report form documents for the programmers to reference
- Addressed client comments on outputs and dataset programs
- Read and conformed with Catalyst Standard Operating Procedures (SOPs)
- Programmed listings and tables from CDISC (Clinical Data Interchange Standards Consortium) data sets including both SDTM (Study Data Tabulation Model) and ADaM (Analysis Dataset Model)

ADDITIONAL INFORMATION

- Proficient in R, SAS, and SOL, while actively working towards proficiency in Python
- Familiar with Java, CSS, and HTML
- Interests: Backpacking, Fishing, Running, and Traveling