SIMON P. WEISENHORN

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EDUCATION

North Carolina State University – Raleigh, NC August 2023
Master of Statistics

University of North Carolina at Chapel Hill – Chapel Hill, NC May 2022
B.S., Statistics and Analytics
Data Science Minor

EXPERIENCE

Ora, Inc. – Chicago, IL September 2023 – May 2025
Biostatistician; Contract research organization specializing in full-service ophthalmology

- Authored four detailed Statistical Analysis Plans (SAPs) ensuring alignment with regulatory requirements (e.g., ICH E9 guidelines) and study-specific objectives defined in clinical protocols.
- Served as the lead statistician on multiple early to mid-phase, multicenter, randomized, placebo-controlled clinical trials in ophthalmology, covering indications such as dry eye disease and retinitis pigmentosa.
- Directed collaborative efforts with cross-functional global teams, including a programming team in Hyderabad, India, to execute statistical deliverables across diverse therapeutic areas.
- Designed and developed comprehensive TLF (Tables, Listings, and Figures) shell documents to standardize reporting formats and streamline programming efforts.
- Conducted thorough reviews of CRFs (Case Report Forms) for consistency, data collection adequacy, and alignment with study endpoints and statistical methodologies.
- Spearheaded the development and documentation of SDTM and ADaM mapping specifications which contributed to the generation of submission-ready datasets in compliance with CDISC standards.
- Programmed high-quality summary tables, subject-level listings, and exploratory graphics to support clinical development decision-making and regulatory submissions.
- Executed all planned and exploratory statistical analyses outlined in SAPs, including subgroup analyses and sensitivity analyses; provided strategic input on data interpretation.
- Performed statistical quality control (QC) and independent reprogramming of key outputs included in final clinical study reports (CSRs), data monitoring committees (DMCs), and data safety monitoring boards (DSMBs).
- Ensured 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.
- Represented the Biostatistics department in regulatory agency meetings, sponsor communications, and cross-functional working groups.
- Oversaw study-level timelines, resource planning, and budgets; monitored out-of-scope work and proactively addressed change orders and client expectations.
- Maintained rigorous compliance with Ora's internal quality systems and industry regulatory standards, including data integrity and ethical conduct 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 SQL, while actively working towards proficiency in Python.
- Familiar with Java, CSS, and HTML.