CAPABILITIES AND EXPERIENCE
ROBERT GERWIEN

WORK EXPERIENCE

Landrich Group (2024 – Present)

- Provide regulatory assistance, clinical trial design advice, protocol development, sample size estimation, statistical analysis plans, statistical analysis, clinical study reports, and manuscript preparation for clients.

Statistical Consulting (2023-Present)

- Provide statistical and publication support for several companies Including Alkeus Pharmaceuticals, Annexon Bioscience, Nox Health, Brain Box Solutions and Immunocore
- Develop regulatory documents including statistical analysis and trial (data) integrity plans.
- Perform *ad-hoc* analyses for publications, and trial-planning including sample size estimation.
- Support analyses for CDRH and CDER regulatory submissions.
- Research areas include oncology, ophthalmology, rare disease/autoimmune disorders, insomnia and traumatic brain injury diagnosis.

Pear Therapeutics (2018 – 2023)

- Provide statistical support and analysis 510k submissions of digital therapeutics to CDRH.
- Participated in clinical trial design including developing an analysis plan and estimation of sample size.
- Provide exploratory analyses of existing data with the objective of identifying correlates with engagement.
- Serve as a statistical expert for clinical advisory and regulatory meetings.
- The primary research area was CBT for addiction and insomnia.

HealtTell (2015 – 2018)

- Developed algorithms to identify biomarkers that are predictive of autoimmune diseases.
- Developed algorithms to facilitate efficient clinical trial design.
- Provide statistical support for assay development and quality control.
- Develop analysis packages for general use.
- Clinical study design and traditional Design of Experiments.
- The primary research area was auto-immune disorders.

Quaticate International (2013 – 2015)

- Provide high quality statistical support to clients.
- Manage assigned projects.
- Manage and support personnel and to assign projects to appropriate personnel.
- Provide sample size estimates, randomization schedules and statistical sections of protocols as required.
- Provide data analysis and statistical reports according to internal reporting analysis plans or the clients specific requirements.
- Write statistical analysis plans for prospective and retrospective clinical trials.
- Provide expertise in 'big-data' analysis such as GWAS and other – omic technologies.
- The primary research areas included neuroscience, oncology and pediatric medicine.
- Assistant to Leadership Team: Scheduling, expense report management, travel arrangement, inbound/outbound call management, Research and Evaluation support.

EXPERIENCE HIGHLIGHTS

Experienced Biostatistician accredited by the American Statistical Association, possessing extensive expertise in algorithm development, statistical data analysis, and modelling within the biotechnology and drug development sectors. Notable focus includes clinical trial design, and analysis (Phase 1-3), translational medicine, and active participation in regulatory meetings with FDA. Strong background in oncology drug development, biomarker identification, and pre-clinical analysis, proficient in experimental design, statistical methods, and adherence to industry standards such as CDISC. Excels in collaborative research environments, employing various statistical packages such as S-plus, SAS, SPSS, Plink, OpenBUGS, and Graph-Pad Prism.

EDUCATION & ACCREDITATION

- Doctor of Philosophy, Biological Sciences – Rutgers University, NJ
- B.S. Biology (Minor in Chemistry) – Fairfield University, CT
- Member of American Statistical Association