CAPABILITIES AND EXPERIENCE
KATIE MILLER

WORK EXPERIENCE

Landrich Group (2024 – Present)

- Provide global statistical and data management activities while managing the end-to-end FDA submission process and actively contributing to outcomes research initiatives. Demonstrate expertise in SAS programming, adept study design, and substantial contributions to statistical analyses, all underscored by a dedicated commitment to advancing clinical research standards and ensuring meticulous data accuracy.

Director of Biostatistics: CANARY MEDICAL (2023 – Present)

- Provide oversight of statistical and data management activities within Canary Medical. Responsibilities include statistical support for regulated and post market studies, clinical strategy and study design, protocol and statistical analysis plan development, sample size calculations, data analysis and SAS programming, writing statistical analysis/clinical study reports, data presentations, and contributing to Clinical Evaluation Reports.

Senior Biostatistician II: PROPHARMA GROUP/M SQUARED ASSOCIATES, INC. (2017 – 2023)

- Responsibilities include statistical support for regulated and post market studies conducted both in the US and outside the US – working with clients on the optimal clinical strategy and study design, protocol and statistical analysis plan development, sample size calculations, data analysis and SAS programming. Experience writing statistical analysis/clinical study reports and submissions to the FDA including Q-sub requests, 510k, PMA, De Novo, and breakthrough device designations. Experience with a large variety of study sizes and designs, including single-arm studies, randomized controlled trials, retrospective studies, literature meta-analysis, and prospective cohort studies, as well as with a large variety of medical devices. Assisted with preparation and attendance at meetings with clients or on behalf of clients, written documents and responses, and other interactions with FDA as well as other regulatory bodies. Oversee other statisticians and statistical programmers.

Biostatistician/Manager of Clinical Evidence: BIOMET ORTHOPEDICS/ZIMMER BIOMET (2010 – 2017)

- Responsibilities included clinical data mining and analysis. Assisted in planning budget, statistical analysis plan, and managing data audit for PMA submission. Reviewed and analyzed of National Joint Registry data. Statistical support for regulated and post market studies conducted both in the US and outside the US – protocol development, study design, sample size calculations, annual reports, and submissions to the FDA. Prepared and reviewed Clinical Evaluation Reports for regulatory registrations. Prepared and reviewed statistical analyses for clinical proofs including journal publications, white papers, and field communications. Attended pre-IDE meetings with FDA. Prepared PMA submissions, Final Study Reports, and Annual Reports Statistical support for outcomes research. Oversaw and managed the Clinical Evidence team including technical writers, database coordinators, statisticians, and clinical evidence specialists.

Biostatistician/SAS Programmer: ZIMMER, INC, (2006 – 2010)

- Responsibilities included statistical support for regulated studies – protocol development, study design, sample size calculations, annual reports, and submissions to the FDA Clinical data mining and analysis. Prepared and reviewed Clinical Evidence Reports. Prepared PMA submissions and Annual Reports. Statistical support for outcomes research (including survival analyses, regression, two sample comparisons, and matched-pair, repeated measures, and others) Assisted in research pertaining to the use of permutation tests to analyze repeated measures data (paper/presentation at Joint Statistical Meetings in August 2007) Programmed automated reports for use by clinical study management using SAS.

EXPERIENCE HIGHLIGHTS

- Seasoned biostatistician and clinical researcher with a rich history in the medical device industry has led statistical and data management activities globally. Successfully manage submissions to the FDA, mentoring teams, and playing a pivotal role in outcomes research. Expertise extends to SAS programming, study design, and significant contributions to statistical analyses, reinforcing a commitment to advancing clinical research and ensuring data accuracy.

EDUCATION & ACCREDIATION

- Masters in Statistics – Miami University, Oxford, OH
- Bachelor of Arts, Major: Mathematics – Taylor University, Upland, IN