

Research Statement

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Dear Professors,

I am writing to express my sincere interest in the faculty position within the Department of Biostatistics & Bioinformatics at Duke University, with a particular focus on clinical trial innovation. My extensive research background in Biostatistics, Bayesian theory, and Bayesian computation coupled with a dedication to advancing the field through complex adaptations, integration of real-world evidence, and exploration of novel endpoints and outcomes, positions me as an ideal candidate for this position.

Research Overview:

My research agenda revolves around addressing critical challenges in the design and analysis of clinical trials for regulatory submission to get approval from regulatory agencies such as U.S. Food and Drug Administration or European Medicines Agency. Over the course of my academic career, I have developed a keen interest in advancing the methodology of clinical trials to enhance their efficiency, ethicality, and relevance in the era of precision medicine.

I have been trained to develop innovative designs from the sponsor's perspective in the industry as a Design Biostatistician. As a result, I am familiar with many guidelines from regulators and have experienced what is acceptable for regulatory submission. I believe that this skill is one of the strengths reflected in my research, as it aligns with the actual good practices of trial designs.

Key Research Areas:

Complex Adaptations:

My work involves the development and application of innovative adaptive trial designs that needs extensive simulations, optimizing efficiency while maintaining statistical rigor (i.e., type I & II error requirement). I have successfully implemented adaptive designs, contributing to a more efficient use of resources and an accelerated pace of clinical development.

Integration of Real-World Evidence:

Recognizing the growing importance of real-world evidence in complementing traditional clinical trial data, my research focuses on developing robust methodologies for integrating and analyzing diverse data sources. This includes the exploration of electronic health records, patient registries, and other real-world data to enhance the generalizability and external validity of clinical trial findings. Additionally, I am familiar with Bayesian information borrowing techniques and have published multiple papers on various topics, not confined to trial design but also encompassing epidemiology, the petroleum industry, wind energy industry, and more.

Novel Endpoints and Outcomes:

In response to the evolving landscape of healthcare and patient-centered care, my research explores the development and validation of novel endpoints and outcomes that better capture the holistic impact of interventions. This includes patient-reported outcomes, biomarker-driven endpoints, and other innovative measures that align with the evolving needs of healthcare stakeholders. For example, I recently published a paper at BMC Trial in order to advocate the use of continuous toxicity information rather than binary toxicity information in Phase I cancer clinical trials.

Collaborative Approach:

I am committed to fostering interdisciplinary collaborations, and I am particularly excited about the prospect of collaborating with Duke University's esteemed faculty members in biostatistics, as well as clinicians and researchers across various disciplines. The collaborative environment at Duke aligns with my vision of translating methodological innovations into practical solutions that positively impact patient care and public health.

Enclosed with this letter, you will find my curriculum vitae, a list of publications. I welcome the opportunity to discuss my research in more detail and explore how my expertise aligns with the goals of the Department of Biostatistics & Bioinformatics at Duke University.

Thank you for considering my application. I look forward to the possibility of contributing to the vibrant research community at Duke.

Sincerely,

Se Yoon Lee, Ph.D.