SE YOON LEE

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EDUCATION

Ph.D. Statistics, Texas A&M University, College Station, U.S.A.

Advisor: Prof. Bani K. Mallick

M.A. Applied Statistics, Yonsei University, Seoul, South Korea

May 2021

Overall GPA: 3.78/4

Feb 2016

Advisor: Prof. Joseph H.T. Kim

Overall GPA: 3.86/4

B.S. Mathematics, Yonsei University, Seoul, South KoreaGraduated with the 2nd highest class rank out of 43 students

Overall GPA: 3.84/4

RESEARCH INTEREST & SPECIALTY

Bayesian High-dimensional Statistical Modeling, Spatial Statistics, Machine Learning/Data Science, Bayesian Analysis

DISSERTATION AND THESIS

- "Bayesian Hierarchical Modeling: Application towards Complex and High-dimensional Data," *Texas A&M University*, Doctoral Dissertation; [**Link**]
- · "Exponentiated generalized Pareto distribution: an alternative to the generalized Pareto distribution," *Yonsei University*, Master's Thesis; [Link]

WORK EXPERIENCE

Edwards Lifesciences.

May 2023 – present Irvine, CA

- Manager, Biostatistics (Permanent Employment)
- Developed an R code to perform unblinded sample size re-estimation (promising zone approach) using CHW test statistics for a hierarchical composite endpoint, employing the Finkelstein and Schoenfeld methodology.
- · Specialized in developing simulation R code for power calculation of Bayesian adaptive design for cardiovascular trials at the regulatory submission level, with expertise in end-to-end coding and Statistical Analysis Plan writing.
- · Provided seminars on the topic of Bayesian Medical Device Trials to train biostatisticians; [Link]
- · Provided advanced biostatistical supports (e.g., power analysis, primary endpoint analyses, clinical trial designs, etc) to cross-functional teams.

Johnson & Johnson. Senior Biostatistician (Permanent Employment)

*Apr 2022 – May 2023*Irvine, CA

- · Developed Bayesian adaptive clinical trials designs to evaluate the safety and effectiveness of medical devices (Bayesian basket trial designs, power-prior designs, Bayesian group sequential designs, etc).
- Provided advanced biostatistical supports (e.g., power analysis, primary endpoint analyses, clinical trial designs, etc) to clinicians with main focus on cardiovascular diseases.
- · Led working groups of experts (Machine Learning/Statistical Methodology & Consulting) as leader
- Led the development of basket trial designs and authored Statistical Analysis Plan for SECURE, a Post-Market Study [ClinicalTrials.gov ID: NCT04750798]

Amgen Inc.

May 2021 – Apr 2022

Scientist - Modeling & Simulations (Permanent Employment)

Thousand Oaks, CA

- Developed Pharmacokinetics/Pharmacodynamics/Cox hazard regression models for Phase I cancer clinical trials of AMG160 to treat a metastatic castration-resistant prostate cancer (mCRPC).
- · Researched machine learning and deep neural network models to fit single dose data for subsequent simulation of multiple dosing scenarios.

Novartis International AG.

Biostatistics Summer Intern (Contract Employment)

May 2020 – Aug 2020 East Hanover, NJ

· Developed a Bayesian linear mixed effect model for patients who have wet age-related macular degeneration to predict best-corrected visual acuity over the maintenance phase and suggest a personalized dose regimen. The proposed model has been trained by actual patients' data from HAWK and HARRIER studies (Number of patients is around 1,800 patients).; [Abstract]

EMD Serono Inc. Merck KGaA.

May 2019 - Aug 2019

Pharmacometrics Summer Intern (Contract Employment)

Billerica, MA

· Developed a Bayesian adaptive clinical trial design in Phase I cancer clinical trials, which aimed at utilizing grade information from the Common Toxicity Criteria for Adverse Events provided by the National Cancer Institute.; [Abstract]; [Poster]

Texas A&M University. Graduate Research/Teaching Assistant

Aug 2016 – May 2021 College Station, TX

· Researched on applications and developments of various statistical models (e.g. non-linear mixed effect model, nonparametric/semiparametric longitudinal model, clustering analysis, classification, hierarchical Poisson model, etc) to various industrial problems arising from biomedical, petroleum, wind energy industries, and COVID-19 outbreak.

PUBLICATIONS

Journal Article

- [1] **Seyoon Lee**, Joseph H.T. Kim. (2018) "Exponentiated generalized Pareto distribution: Properties and applications towards extreme value theory," *Communications in Statistics Theory and Methods*, 48:8, 2014-2038
- [2] <u>Se Yoon Lee</u>, Bowen Lei, and Bani K. Mallick. (2020) "Estimation of COVID-19 spread curves integrating global data and borrowing information," *PLOS ONE*; [Github]
- [3] <u>Se Yoon Lee</u>*, Kahkashan Afrin*, Ashif Iquebal*, Mostafa Karimi*, Allyson Larsen*, and Bani K Mallick*. (2020) "Directionally Dependent Multi-View Clustering Using Copula Model," *PLOS ONE* (* : equal contribution, authors are alphabetically ordered in the last name.)
- [4] <u>Se Yoon Lee</u> and Bani K. Mallick. (2021) "Bayesian Hierarchical modeling: application towards production results in the Eagle Ford Shale of South Texas," *Sankhyā: The Indian Journal of Statistics, Series B*; [Github]
- [5] <u>Se Yoon Lee</u>. (2021) "Gibbs sampler and coordinate ascent variational inference: a set-theoretical review," *Communications in Statistics Theory and Methods*
- [6] <u>Se Yoon Lee</u>, Alain Munafo, Pascal Girard, and Kosalaram Goteti. (2022) "Optimization of dose selection using multiple surrogates of toxicity as a continuous variable in Phase I cancer trial," *Contemporary Clinical Trials*; [Github]
- [7] <u>Se Yoon Lee</u>. (2022) "Bayesian Nonlinear Models for Repeated Measurement Data: An Overview, Implementation, and Applications," *Mathematics*
- [8] Se Yoon Lee. (2022) "The Use of a Log-Normal Prior for the Student t-Distribution," Axioms
- [9] Hyung-Kyu Chae, Hyun Jeong Hong, <u>Se Yoon Lee</u>, Jung-Hoon Park, Woo Joo Choi, Seungkuk Oh, Seoyeoun Ji, Yeon-Jung Hong. (2022) "Factors Affecting the Outcome of Medical Treatment in Cats with Obstructive Ureteral Stones Treated with Tamsulosin: 70 Cases (2018–2022)," *Veterinary Sciences*
- [10] Hyung-Kyu Chae, Ju-Yeon Jeong, <u>Se Yoon Lee</u>, Hyun-Min Hwang, Kyoung-In Shin, Jung-Hoon Park, Seo-yeoun Ji, Yeon-Jung Hong. (2023) "Clinical Outcomes in Dogs Undergoing Cholecystectomy via a Transverse Incision: A Meta-Analysis of 121 Animals Treated between 2011 and 2021," *Veterinary Sciences*

- [11] Abhinav Prakash, **Se Yoon Lee**, Xin Liu, Lei Liu, Bani Mallick, Yu Ding. (2023) "A Bayesian hierarchical model to understand the effect of terrain on wind turbine power curves," *IEEE Transactions on Sustainable Energy*
- [12] <u>Se Yoon Lee</u>. (2023) "A flexible dose-response modeling framework based on continuous toxicity outcomes in phase I cancer clinical trials," *BMC Trials*
- [13] <u>Se Yoon Lee</u>. (2024) "Using Bayesian Statistics in Confirmatory Clinical Trials in the Regulatory Setting: A Tutorial Review," *BMC Medical Research Methodology*
- [14] **Se Yoon Lee**. (2024) "Eliciting the discount parameter in a power prior method on the basis of the type I error consideration," *Statistics in Biopharmaceutical Research*

Conference Paper/Poster

- [1] <u>Se Yoon Lee</u>, Shankar Lanke, Alain Munafo, Pascal Girard, and Kosalaram Goteti. (2020) "Optimization of dose selection using multiple surrogates of toxicity as continuous variable in Phase I cancer trial," *American Conference on Pharmacometrics II*
- [2] <u>Se Yoon Lee</u>, Po-Wei Chen, Naren Narayanan, Sandeep Dutta, and Malidi Ahamadi. (2022) "Performance of nlmixr vs NONMEM for the Estimation of Pharmacometrics Models with Different Degrees of Non-linearity; an AMGEN experience," *American Society for Clinical Pharmacology & Therapeutics 2022 Annual Meeting*

Under review

- [1] **Se Yoon Lee**, Peng Zhao, Debdeep Pati, Bani K. Mallick. (2024+) "Tail-adaptive Bayesian Shrinkage", *Major revision invited for Electronic Journal of Statistics*
- [2] **Se Yoon Lee**. (2024+) "Constrained borrowing of external control data based on type I error consideration in a power prior method," *Submitted*

PROFESSIONAL ACTIVITIES

Invited Peer Reviewers

- · Statistics in Medicine (Impact Factor: 2.373)
- · Biostatistics (Impact Factor: 1.8)
- · European Journal of Clinical Investigation (Impact Factor: 3.481)
- · Artificial Intelligence Review (Impact Factor: 8.139)
- · The Journal of Clinical Pharmacology (Impact Factor: 3.126)
- · Frontiers in Public Health (Impact Factor: 3.709)
- · The R Journal (Impact Factor: 3.984)
- · Computational Geosciences (Impact Factor: 2.948)
- · Journal of Applied Statistics (Impact Factor: 1.416)

HONORS AND AWARDS

Travel fund for an invited talk at Yonsei University	Dec 2019
Given to an invited speaker for the presentation	
Travel fund for an invited talk at University of Michigan	Jun 2019
Given to an invited speaker for an annual meeting about wind energy	
Travel fund for poster presenter for the Houston Geological Society	Mar 2018
Given to a poster presenter	
Anant Kshirsagar fellowship	Jul 2018
Given to graduate students who demonstrate excellence in making progress in research	
The 1st place prize in SETCASA poster session in 2018	Apr 2018
Given to only one winner for the poster session	-
Graduate student travel award for JSM	Jul 2017, 2018
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Given to graduate students who make a presentation at the conference

INVITED TALKS

•	"Important statistical issues in Bayesian medical device trials in regulatory settings"; [Slide] Organization: 2023 Orange County Biostatistics Symposium	Sep 2023
٠	"Prediction of best-corrected visual acuity for wet age-related macular degeneration patients in HAWK and HARRIER studies via a Bayesian hierarchical linear model" Organization: Novartis International AG, Internship Project Presentation	Aug 2020
•	"Estimation of COVID-19 spread curves integrating global data and borrowing information" Organization: Mathophilia 2020, IQAC, Banwarilal Bhalotia College, Asansol, India	Jul 2020
•	"Bayesian Hierarchical Model: Application towards Wind Farm Data" Organization: National Science Foundation, University of Connecticut, Mansfield, CT, U.S.A.	Jun 2020
•	"Continuous shrinkage prior revisited: a collapsing behavior and remedy"; [Abstract] Organization: Yonsei University, Department of Applied Statistics, Seoul, South Korea	Dec 2019
•	"Tutorial: understanding offshore wind energy data and spatial modeling" Organization: National Science Foundation, University of Michigan, Ann Arbor, MI, U.S.A.	Jun 2019

SOFTWARE

Software used in papers

- · Bayesian Hierarchical Richards Model; Written in R; [Download]; [Github]
- $\cdot \ \mathsf{Spatial} \ \mathsf{Weibull} \ \mathsf{Model} \ ; \mathsf{Written} \ \mathsf{in} \ R \ ; \textbf{[Github]}$
- bayesestdft; Written in R; [Github]

SKILLS

Language	Fluent in English and Korean; Elementary in Chinese and Japanese
Computer Language	Proficient in R, Python, SQL, Microsoft Access, SAS, and NONMEM
Certificate	Cognigen NONMEM Workshop