

SE YOON LEE

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PROFESSIONAL SUMMARY

- An experienced statistician with over 3 years of experience in the healthcare industry (medical devices and pharmaceutical drugs). Extensive experience in study designs, statistical operations, and scientific publications across a broad range of therapeutic areas, including cardiovascular disease, oncology, and ophthalmology
- Major functional contributor to regulatory approvals in numerous product and clinical applications across the globe. Specializing in Bayesian adaptive design, complex modeling and simulation, data integration, systematic reviews and meta-analysis, and scientific publications
- Expert in R/SAS for the development of simulation-based sample size calculations for complex and innovative trial designs and NONMEM for population pharmacokinetic/pharmacodynamic (PK/PD) models
- Author of many top peer-reviewed statistical and scientific articles, and invited peer-reviewer for top-tier statistical methodology journals and scientific journals.

EDUCATION

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

Advisor: Prof. Bani K. Mallick

May 2021

Overall GPA: 3.78/4

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

Advisor: Prof. Joseph H.T. Kim

Feb 2016

Overall GPA: 3.86/4

B.S. Mathematics, Yonsei University, Seoul, South Korea

Graduated with the 2nd highest class rank out of 43 students

Feb 2013

Overall GPA: 3.84/4

RESEARCH INTEREST & SPECIALTY

Clinical Trials, Bayesian Adaptive Design, Group Sequential Design, Survival Analysis, Modeling & Simulation

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.
Manager, Biostatistics

May 2023 – present
Irvine, CA

- 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.*Apr 2022 – May 2023***Senior Biostatistician**

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**

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.*May 2020 – Aug 2020***Biostatistics Summer Intern**

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**

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.*Aug 2016 – May 2021***Graduate Research/Teaching Assistant**

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] [Se Yoon Lee](#), Bowen Lei, and Bani K. Mallick. (2020) "Estimation of COVID-19 spread curves integrating global data and borrowing information," *PLOS ONE* ; [[Github](#)]
- [3] [Se Yoon Lee](#)^{*}, Kakhkashan 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] [Se Yoon Lee](#) 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] [Se Yoon Lee](#). (2021) "Gibbs sampler and coordinate ascent variational inference: a set-theoretical review," *Communications in Statistics - Theory and Methods*

- [6] **Se Yoon Lee**, 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] **Se Yoon Lee**. (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, **Se Yoon Lee**, 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, **Se Yoon Lee**, 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] **Se Yoon Lee**. (2023) “A flexible dose-response modeling framework based on continuous toxicity outcomes in phase I cancer clinical trials,” *BMC Trials*
- [13] **Se Yoon Lee**. (2023) “Using Bayesian Statistics in Confirmatory Clinical Trials in the Regulatory Setting: A Tutorial Review,” *BMC Medical Research Methodology*

Conference Paper/Poster

- [1] **Se Yoon Lee**, 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] **Se Yoon Lee**, 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. (2023+) “Tail-adaptive Bayesian Shrinkage”; [\[Slides\]](#)
- [2] **Se Yoon Lee**. (2024+) “Formula for the effective sample size of the power prior model” *Revision invited to Statistics in Biopharmaceutical Research*

PROFESSIONAL ACTIVITIES

Invited Peer Reviewers

- 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)
- Statistics in Medicine (Impact Factor: 2.373)
- 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

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| Travel fund for an invited talk at Yonsei University | <i>Dec 2019</i> |
| Given to an invited speaker for the presentation | |
| Travel fund for an invited talk at University of Michigan | <i>Jun 2019</i> |
| Given to an invited speaker for an annual meeting about wind energy | |
| Travel fund for poster presenter for the Houston Geological Society | <i>Mar 2018</i> |

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

Given to graduate students who make a presentation at the conference

INVITED TALKS

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

SOFTWARE

Software used in papers

- Bayesian Hierarchical Richards Model ; Written in R ; [\[Download\]](#) ; [\[Github\]](#)
- Spatial Weibull Model ; Written in R ; [\[Github\]](#)
- 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