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. *May 2021*
Advisor: Prof. Bani K. Mallick Overall GPA: 3.78/4
M.A. Applied Statistics, Yonsei University, Seoul, South Korea *Feb 2016*
Advisor: Prof. Joseph H.T. Kim Overall GPA: 3.86/4
B.S. Mathematics, Yonsei University, Seoul, South Korea *Feb 2013*
Graduated with the 2nd highest class rank out of 43 students 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. *May 2023 – present*
Manager, Biostatistics (Permanent Employment) 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 (Permanent Employment) 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. *May 2020 – Aug 2020*
Biostatistics Summer Intern (Contract Employment) 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. *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***, 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] **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**. (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] **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 11*

[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+) "Constrained borrowing of external control data based on type I error consideration in a power prior method, " *Submitted*

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

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*
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