

SE YOON LEE

1859 S Union St 37 Anaheim, CA, 92805
(979) · 888 · 4107 ◇ seyoonlee.stat.math@gmail.com
<https://sites.google.com/view/seyoonlee>

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

Bayesian Analysis, Bayesian Adaptive Design, Bayesian High-dimensional Statistical Modeling, Spatial Statistics

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.
- Served as a Teaching Assistant for both undergraduate and graduate courses.

PUBLICATIONS**Journal Article (*: corresponding author / Q1 (best),2,3,4: SJR Quartile)**

- [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 [\[Q3\]](#)
- [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*; [\[Github\]](#) [\[Q1\]](#)
- [3] Kakhkashan Afrin*, Ashif Iquebal*, Mostafa Karimi*, Allyson Larsen*, [Se Yoon Lee](#)*, 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.) [\[Q1\]](#)
- [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* ; [\[Github\]](#) [\[Q3\]](#)
- [5] [Se Yoon Lee](#)*. (2021) "Gibbs sampler and coordinate ascent variational inference: a set-theoretical review," *Communications in Statistics - Theory and Methods* [\[Q3\]](#)
- [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* ; [\[Github\]](#) [\[Q1\]](#)
- [7] [Se Yoon Lee](#)*. (2022) "Bayesian Nonlinear Models for Repeated Measurement Data: An Overview, Implementation, and Applications," *Mathematics* [\[Q2\]](#)
- [8] [Se Yoon Lee](#)*. (2022) "The Use of a Log-Normal Prior for the Student t-Distribution," *Axioms* [\[Q3\]](#)
- [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* [\[Q1\]](#)

- [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* [Q1]
- [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* [Q1]
- [12] **Se Yoon Lee***. (2023) "A flexible dose-response modeling framework based on continuous toxicity outcomes in phase I cancer clinical trials," *BMC Trials* [Q2]
- [13] **Se Yoon Lee***. (2024) "Using Bayesian Statistics in Confirmatory Clinical Trials in the Regulatory Setting: A Tutorial Review," *BMC Medical Research Methodology* [Q1]
- [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* [Q1]
- [15] **Se Yoon Lee***, Peng Zhao, Debdeep Pati, Bani K. Mallick. (2024+) "Tail-adaptive Bayesian Shrinkage", *Major revision invited for Electronic Journal of Statistics* [Preprint] [Q1]

Under Review

- [1] **Se Yoon Lee***. (2024+) "Constrained borrowing of external control data based on type I error consideration in a power prior method," *Submitted (contact me for the preprint)*
- [2] **Se Yoon Lee***. (2024+) "A Note on the Sample Size Formula for a Win Ratio Endpoint by Yu and Ganju," *Submitted (contact me for the preprint)*

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*

PROFESSIONAL ACTIVITIES

Invited Peer Reviewers

- Statistics in Medicine (Impact Factor: 2.373)
- Biostatistics (Impact Factor: 1.8)
- Contemporary Clinical Trials Communications (Impact Factor: 1.4)
- 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

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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

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|--------------------------|------------------------------------------------------------------|
| 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 |

REFERENCES

| | |
|------------------------|-----------------------------------------------------------------------|
| Bani K. Mallick | Distinguished Professor, Texas A&M University, bmallick@stat.tamu.edu |
| Debdeep Pati | Professor, Texas A&M University, debdeep@stat.tamu.edu |
| Samiran Sinha | Professor, Texas A&M University, sinha@stat.tamu.edu |
| Alan Dabney | Professor, Texas A&M University, adabney@stat.tamu.edu |