LEI LI

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Professional Summary

- AI consultant, familiar with modern popular deep learning techniques with application to quant theory, drug discovery, and automation.
- Seasoned PhD biostatistician with extensive experience from both regulatory agencies and leading biotech pharmaceutical companies. Specializing in both clinical trial designs and applications to advanced biostatistical methods.
- Statistical project leader on moderate to large size projects varying from phase I to phase III with hands on submission experience.
- Outstanding Communication and Leadership Skills.

Professional Experience

Independent AI and Stats Consultant *06/2023 – Present*

Statistical Project Leader, Deputy Director – Sanofi *06/2023 – 04/2025*

- Vaccine: Leading several vaccine projects:
    - Project leader on periodontal disease vaccine study (translational study, phase I/II): I lead on the protocols and SAPs design, where novelly I apply multinomial logistic regression method for biomarkers analysis. Also, I use Bayesian decision by design framework to help team with the Go/No Go decision-making process.
    - Project leader on Acne vaccine project (two phase I/II studies): I lead on the protocols and SAPs design, where the Multiple Comparison Procedure Modeling (MCPMod) is proposed for both sample size determination and dose-finding. Also, I collaboratively perform daily statistical activities such as ESDR, DSUR.
    - Project Leader on phase III rabies vaccine: hands on experience on submissions to FDA and EMA (e.g., pre-BLA and BIMO preparation, ISE, ISS submission).
    - Study statistician on Expec project for Escherichia coli phase III study E.mbrace. This is a Bayesian group sequential design study, I mainly conduct efficacy and futility analysis using Bayesian method.
- Statistical Innovation Group: As statistical expert, I lead several statistical methodology developments:
    - Dose Finding method: Using the Multiple Comparison Procedure Modeling (MCPMod) framework,
    - Decision by Design (DxD) framework: we use Bayesian method to facilitate the GO/NO GO decision-making process from phase I/II towards phase III.
    - Develop the Group Sequential Design theory under the Binomial distribution with application to vaccines.
- Rare disease: Co-lead several phase III hemophilia studies: i) develop/validate efficacy results including the primary and key secondary analyses (e.g., ISE); ii) create and validate safety results and outputs (e.g., ISS); iii) work on new pivotal table shells/CSR including complex patient flowchart; iv) perform adhoc analysis to support requests from other teams identifying key patterns affecting efficacy endpoints.

Principal BioStatistician – Edwards Lifesciences *04/2022 – 04/2023*

- Lead Biostatistician on two early feasibility studies (i.e., phase I/II) of cardiovascular projects: i) Develop clinical trial statistical analysis plan (SAP), data specs, and statistical analysis for the early feasibility projects; ii) Lead the statistical data analysis with mixed modeling techniques and win ratio methods; iii) Co-lead the statistical analysis part for the publication paper “Left Atrial to Coronary Sinus Shunting for Treatment of Symptomatic Heart Failure” at JACC cardiovascular interventions journal; iv) Mentor junior level staff onboard and other biostatistics business

Mathematical Statistician – FDA/CDRH *09/2020 – 04/2022*

- Leading reviewer of RWD/RWE submissions using propensity score methodology including the areas of breast reconstruction, cervical artificial disc, etc.
- Review and provide professional statistical memo for therapeutic and diagnostic medical devices such as general surgical and orthopedic devices, in invo and in vitro diagnostic devices, etc.
- Hands on experience with all types of medical device submissions such as pre-submissions, IDEs, 510(k)s, De Novo, and PMA.

Graduate Teaching Assistant, George Mason University *08/2018 to 05/2020*

Education and Training

Ph.D. in Statistics, George Mason University *05/2020*
- Thesis: Generalize EM algorithm with application to healthcare data

MS in Statistics, George Washington University *05/2015*

BS in Mathematics, Shandong University (China) *06/2013*

Statistical Expertise

- MMRM, Group Sequential Design, Bayesian Design, Adaptive Design, Real World Evidence, dose-response finding, Win Ratio Approach, Go/No Go Decision-making, MCPMod, Machine Learning on biostatistics, Causal Inference, Permutation Test.
- Statistical Software: Substantive experience on SAS, R, Python

Publications

- Vidyashankar, A.N., **Li, L.** (2019) "Ancestral Inference for Branching Processes in Random Environments and an Application to Polymerase Chain Reaction". *Stochastic Models,* 1-20, Taylor & Francis
- **Li, L.**, Vidyashankar, A.N., Diao, G., Ahmad, E. (2019) "Robust Inference after Random Projections via Hellinger Distance for Location-scale Family". *Entropy,* 21, 348
- **Li, L.**, Vidyashankar, A.N. (2019) "Divergence Methods for Models with Latent Structure: Theory and Algorithms". *Pre-print version*
- **Li, L.**, Vidyashankar, A.N., Clark C., Doyle, L.J. (2019) "Statistical Framework for Measuring and Assessing Security Risk in Healthcare Databases". *Pre-print version*

Selected Professional Presentations

- Joint Statistical Meeting, Denver, CO *07/2019*
  Presentation titled "Divergence Based Inference for High Dimensional GLMM"
- ICORS-LACSC Robust Statistics Conference, Guayaquil, Ecuador *05/2019*
  Presentation titled "Divergence Methods for Models with Latent Structure: Theory and Algorithms"
- Joint Statistical Meeting, Vancouver, Canada *07/2018*
  Presentation titled "Privacy Analytics for Healthcare Data in Social Media via Divergence Techniques"
- Joint Statistical Meeting, Baltimore, MD *07/2017*
  Presentation titled "Robust Estimate of Re-identication Risk In Complex Healthcare Data"

Selected Awards

- Herculean Team Award Finalists, Edwards Lifesciences *Mar 2023*
- Innovative Study Design Award Finalists, Edwards Lifesciences *Mar 2023*
- Operational Excellence Award Finalists, Edwards Lifesciences *Mar 2023*
- Outstanding Graduate Student, Washington Statistical Society *May 2017*