

# LEI LI

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## Professional Summary

- AI consultant, familiar with modern popular deep learning techniques with application to healthcare, finance 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

### Founder – LunarAI LLC

04/2025 – Present

- Provide AI, stats, and biostats consulting services.

### 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 biostatistics activities.

#### 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 vivo 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

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#### Ph.D. in Statistics, George Mason University

05/2020

- Thesis: DM algorithm with application to healthcare data

#### MS in Statistics, George Washington University

05/2015

#### BS in Mathematics, BS in Finance (dual degree) Shandong University (China)

06/2013

### Statistical Expertise

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- 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

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- Li, L. (2025) "Anytime-valid Clinical Trial Design: Second-order Efficiency and Expected Stopping Time". *Pre-print version*
- Li, L. (2025) "A Unified Framework for Group Sequential Design". *Pre-print version*
- Li, L., Vidyashankar, A.N. (2025) "Divergence Methods for Models with Latent Structure: Theory and Algorithms". *Pre-print version*
- 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., Clark C., Doyle, L.J. (2019) "Statistical Framework for Measuring and Assessing Security Risk in Healthcare Databases". *Pre-print version*
- Li, L., Vidyashankar, A.N., Clark C., Doyle, L.J. (2019) "Privacy Analytics for Healthcare Data in Social Media via Divergence Techniques". *Pre-print version*
- 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

### Selected Professional Presentations

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- Invited Talk at George Mason University, VA, 02/2026  
Presentation titled "A Unified Framework for Group Sequential Design"
- Invited Talk at Temple University, PA, 10/2025  
Presentation titled "DM algorithm for Data with Latent Structure: Theory and Algorithm"
- Invited Talk at University of Delaware, DE, 10/2025  
Presentation titled "DM algorithm for Data with Latent Structure: Theory and Algorithm"

- Joint Statistical Meeting, Nashville, TN 08/2025  
Presentation titled "Studentized Permutation Test with Application to Vaccine Study"
- Invited Talk at Auburn University, AL, 04/2021  
Presentation titled "Robust Method for Finite Mixture Regression"
- FDA/ASA Conference, Silver Spring, MD, 09/2021  
Presentation titled "Propensity Score Methodology applied to Clinical Study: Practice and Issues"
- 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-identification Risk in Complex Healthcare Data"

### Selected Awards

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| • Herculean Team Award Finalists, Edwards Lifesciences          | <i>Mar 2023</i> |
| • Innovative Study Design Award Finalists, Edwards Lifesciences | <i>Mar 2023</i> |
| • Operational Excellence Award Finalists, Edwards Lifesciences  | <i>Mar 2023</i> |
| • Outstanding Graduate Student, Washington Statistical Society  | <i>May 2017</i> |