LEI LI

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Professional Summary

- Ph.D. biostatistician and former FDA/CDRH mathematical statistician with expert-witness and consulting experience in clinical trials, medical devices, adverse-event incidence analyses, and FDA clearance probability calculations.
- Primary statistical reviewer experience for medical-device submissions including PMA, De Novo, 510(k), IDE, pre-submission, and real-world evidence studies.
- Clinical development statistician with expertise in phase I-IV studies, vaccine development, rare diseases, cardiology, real-world evidence, Bayesian and adaptive trial design, safety assessment, and regulatory submissions.
- Hands-on regulatory submission experience including BLA, NDA, IND, PMA, ISE, ISS, pre-BLA, BIMO preparation, protocols, SAPs, CSR tables, and pivotal statistical outputs.
- Invited speaker, regulatory presenter, teaching assistant, and statistical project leader experienced in explaining complex methods to clinical, regulatory, litigation, and cross-functional audiences.

Expert Witness Experience

Confidential Medical Device Litigation - Defense Consulting Expert **2026**

- Evaluated adverse-event incidence analyses for medical-device litigation.
- Assessed FDA clearance probability calculations and related statistical methodology.
- Assisted counsel with statistical, medical-device, and regulatory issues in a consulting-expert role.

Confidential Pharmaceutical Regulatory Matter - Consulting Expert **2026**

- Evaluated evidence-generation strategy and FDA regulatory considerations for a pharmaceutical development matter.
- Assessed clinical and biomarker evidence gaps and recommended an FDA-aligned study approach.
- Advised on 505(b)(2) pathway considerations and minimal-evidence strategy.

Professional Experience

Expert Witness / Statistical Consultant - LunarAI LLC **08/2025 - Present**

- Provide expert-witness and statistical consulting in matters involving medical devices, clinical trials, adverse-event incidence analyses, and FDA clearance probability calculations.
- Advise an AI drug-discovery startup on 505(b)(2) pathway strategy, clinical and biomarker gap analysis, and FDA-aligned study design.
- Conduct active research in biostatistics and clinical-trial methodology, including probabilistic win ratio methods, sample-size re-estimation, group sequential designs, sufficient dimension reduction, and robust diffusion models.
- Designed an automated AI platform for tables, figures, and listings validation for industry use (demo: https://github.com/lunarai-llc/tfl-validator).

Statistical Project Leader - Sanofi **06/2023 - 04/2025**

- Led statistical strategy for multiple vaccine projects, including translational and phase I/II studies; contributed to protocol and SAP design; applied multinomial logistic regression for biomarker analyses; and used Bayesian Decision by Design methods to support Go/No-Go decisions.
- Led statistical work for two phase I/II acne vaccine studies, proposing Multiple Comparison Procedure Modeling (MCPMod) for sample-size determination and dose-finding and supporting ESDR, DSUR, and other routine statistical deliverables.
- Served as statistical project leader for a phase III rabies vaccine program, with hands-on FDA and EMA submission activities including pre-BLA, BIMO preparation, ISE, and ISS.
- Served as study statistician for the phase III E.mbrace Escherichia coli vaccine study using a Bayesian group sequential design; conducted efficacy and futility analyses using Bayesian methods.

- Led statistical methodology development in dose-finding, Decision by Design, and binomial group sequential design for vaccine applications.
- Co-led phase III hemophilia studies in rare disease; developed and validated primary and key secondary efficacy analyses, ISE and ISS outputs, safety outputs, pivotal table shells, CSR content, patient flowcharts, and ad hoc analyses supporting cross-functional requests.

Principal Biostatistician - Edwards Lifesciences **04/2022 - 04/2023**

- Led biostatistical work for two cardiovascular early feasibility studies, including SAP development, data specifications, and statistical analyses.
- Led statistical analyses using mixed modeling techniques and win ratio methods; co-led the statistical analysis for the publication "Left Atrial to Coronary Sinus Shunting for Treatment of Symptomatic Heart Failure" in JACC: Cardiovascular Interventions.
- Mentored junior biostatistics staff and supported cross-functional clinical development activities.

Mathematical Statistician / Primary Statistical Reviewer - FDA/CDRH **09/2020 - 04/2022**

- Served as primary statistical reviewer for medical-device submissions including PMA, De Novo, 510(k), IDE, pre-submission, and real-world evidence studies.
- Led statistical review of real-world evidence submissions using propensity-score methodology, including matters involving breast reconstruction and cervical artificial disc devices.
- Reviewed and authored statistical memoranda for therapeutic and diagnostic medical devices, including general surgical, orthopedic, in vivo diagnostic, and in vitro diagnostic devices.

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

Education and Training

- Ph.D. in Statistics, George Mason University, 05/2020. Thesis: Divergence Minimization Algorithm with Application to Healthcare Data.
- M.S. in Statistics, George Washington University, 05/2015.
- B.S. in Mathematics and B.S. in Finance (dual degree), Shandong University (China), 06/2013.

Statistical and Regulatory Expertise

Clinical trial design; medical-device evaluation; real-world evidence; adverse-event incidence analysis; Bayesian and adaptive designs; group sequential design; sample-size re-estimation; dose-response finding; MCPMod; MMRM; win ratio methods; causal inference; permutation tests.

Regulatory submissions and review: PMA, De Novo, 510(k), IDE, pre-submission, BLA, NDA, IND, ISE, ISS, pre-BLA, BIMO preparation, SAPs, protocols, CSR tables. Statistical software: SAS, R, Python.

Peer-Reviewed Publications

- Dong, Y.X., & Li, L. (2026). "On Marginal Coordinate Test with Multivariate Responses." Journal of Systems Science & Complexity.
- 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.
- 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 Research Manuscripts and Preprints

- Li, L., Xu, L.H., & Friede, T. (2026). "A Sequential Studentized Permutation Test for Vaccine Efficacy." Preprint.
- Li, L. (2026). "EM Algorithm for Blinded Sample Size Re-estimation." Preprint.
- Li, L. (2026). "Probabilistic Win Ratio Method." Preprint.
- Li, L. (2025). "Anytime-valid Clinical Trial Design: Second-order Efficiency and Expected Stopping Time." Preprint.
- Li, L. (2025). "A Unified Framework for Group Sequential Design." Preprint.
- Li, L., & Vidyashankar, A.N. (2025). "Divergence Methods for Models with Latent Structure: Theory and Algorithms." Submitted to JASA; under review.

Selected Professional Presentations and Teaching

- Scheduled invited talk, Data Science, Statistics & Data Visualization Conference, Italy, 07/2026. Presentation: "Robust and Efficient Methods for Diffusion Models."
- Invited talk, ICSA Applied Statistics Symposium, Fairfax, VA, 06/2026. Presentation: "Robust and Efficient Methods for Diffusion Models."
- Invited talk, George Mason University, VA, 02/2026. Presentation: "A Unified Framework for Group Sequential Design."
- Invited talk, Temple University, PA, 10/2025. Presentation: "Divergence Minimization Algorithm for Data with Latent Structure: Theory and Algorithm."
- Invited talk, University of Delaware, DE, 10/2025. Presentation: "Divergence Minimization Algorithm for Data with Latent Structure: Theory and Algorithm."
- Joint Statistical Meetings, Nashville, TN, 08/2025. Presentation: "Studentized Permutation Test with Application to Vaccine Study."
- FDA/ASA Conference, Silver Spring, MD, 09/2021. Presentation: "Propensity Score Methodology Applied to Clinical Study: Practice and Issues."
- Invited talk, Auburn University, AL, 04/2021. Presentation: "Robust Method for Finite Mixture Regression."
- Graduate Teaching Assistant, George Mason University, 08/2018 - 05/2020.

Selected Awards

- Herculean Team Award Finalist, Edwards Lifesciences, 03/2023.
- Innovative Study Design Award Finalist, Edwards Lifesciences, 03/2023.
- Operational Excellence Award Finalist, Edwards Lifesciences, 03/2023.
- Outstanding Graduate Student, Washington Statistical Society, 05/2017.