Ning Lyu, Ph.D.

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Summary

I am a post-doctoral research fellow at the Harvard-MIT Center for Regulatory Science and Brigham and Women's Hospital where I conduct pediatric pharmacoepidemiology studies. My research focuses on the areas: (1) Use of advanced quantitative methodologies to generate real-world evidence from diverse databases, including insurance claims data (Optum/MarketScan/ Medicaid/TCHP/HUMANA), electronic medical records (IQVIA/TriNetX), registry data (COTA), and national surveys (NAMCS/HNAMCS/MEPS). (2) Comparative effectiveness analysis of treatment efficacy, safety, and health outcomes through different therapeutic areas to generate evidence that supports both regulatory and healthcare decision-making.

Education

PhD	Pharmaceutical Health Outcome and Policy	University of Houston	12/2023
MS	Econometrics and Quantitative Economics	Texas A&M University	06/2018
BS	Economics	Sichuan University	06/2014

Professional Experience

Post-doctoral Research Fellow **09/2024 - present**

Harvard-MIT Center for Regulatory Science, Harvard Medical School – Boston, MA

- Directed the design and execution of real-world evidence (RWE) studies assessing medication safety and effectiveness in children using national claims database, aligning evidence generation with regulatory and clinical decision-making needs.
- Developed and led a research initiative examining FDA approval patterns of biologic therapies in pediatric populations, with a focus on regulatory impact and access implications.

Post-doctoral Research Fellow **07/2024 - present**

Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital – Boston, MA

- Generated evidence regarding the safety of medications using advanced epidemiological and statistical methods applied primarily to large databases derived from health data collected in routine medical care.
- Led two pediatric randomized controlled trials (RCT) emulation using real-world evidence (RWE), evaluating alternative approaches to minimize bias when emulating RCTs in pediatric populations.
- Compared the risk of infections between biologic therapies in pediatric patients with inflammatory bowel disease using nationwide real-world data.

Post-doctoral Fellow **04/2024 - 07/2024**

University Of Houston College of Pharmacy - Houston, TX

- Engaged in an FDA contract application focusing on non-biological complex drugs (NBCD), actively contributing to real-world evidence (RWE) research within this domain.
- Led the project of Comparing Effectiveness and Safety of Glatopa and Copaxone in Patients with Multiple Sclerosis.
- Contributed to the development of R01, K-grant applications through comprehensive writing and rigorous analysis in pharmacoepidemiology research.

Graduate Research Assistant **08/2018 - 12/2023**

University Of Houston College of Pharmacy - Houston, TX

- *Doctoral dissertation*: Identifying, predicting, and managing Antipsychotic-Induced Weight Gain (AIWG) in a large national EMR (IQVIA) cohort of pediatric second-generation antipsychotic (SGA) recipients. .
    - Methods: Group-based trajectory model, Prognostic-based machine learning models, piecewise mixed-effect regression model.

- Performed a retrospective analysis to compare standard-of-care therapy's clinical efficacy and toxicities in historic controls with CAR-BCMA T cell (CT053) in patients with relapsed and/or refractory multiple myeloma (MM).
- Assisted in successfully applying and completing several national grants, including R03, R21, and AHRQ, contributing extensively to writing, analysis, and subsequent publication of research findings.

Outcomes and Evidence Summer Intern **06/2021- 08/2021**

Guardant Health -Palo Alto, CA

- Supported internal data investigations of Guardant INFORM using the advanced programming skillset.
- Validated the survival rate of patients with EGFR/ALK mutations in non-small cell lung cancer (NSCLC) treated with targeted therapies, utilizing the Guardant360 database, to assist in generating robust real-world evidence to inform strategic decisions.
- Worked closely with the product team and contributed to algorithm design and validation.

Data Analyst (Part-time) **09/2017 - 06/2018**

Texas A&M University – College Station, TX

- Analyzed the utilization and expenditures of diabetic medicines and used the two-part model to solve the panel survey data from Medical Expenditure Panel Survey (MEPS) in STATA.
- Conducted retrospective observational study to evaluate opioid-related healthcare resource utilization and costs in Texas using 2016 Texas Inpatient, Outpatient, and Emergency Department Public Use Data.

Teaching and Mentoring Experience

Mentor **11/2023 - 09/2024**

Tuft's Medical school – Boston, MA

- Guided one Tufts University undergraduate student to conduct research related to Medication use in children with ADHD using MEPS data

Graduate Teaching Assistant **08/2018 - 06/2020**

University Of Houston College of Pharmacy - Houston, TX

- Assisted in PharmD courses, including course development, lab preparation, grading, and proctoring

Ongoing Research Projects

Comparative Risk of Infections with Biologics in Pediatric Patients with IBD **09/2024 - present**

- Compared the risk of infections among children with inflammatory bowel disease using the Merative MarketScan Commercial Database and Optum Clinformatics Database
  - Compared first line therapies: Infliximab v Adalimumab.
  - Compared second line therapies: Vedolizumab v Ustekinumab,
  - Compared Infliximab and biosimilars

FDA Licensed (Approved) Biologic Drugs for Use in Children, 1965-2024 **09/2024 - present**

- Assessed 40% biologics had pediatric labeling approval by FDA from 1965 through 2024 and biologic use increased over time in children using real-world data from 2004 through 2024.

Pediatric Randomized Controlled Trials (RCT) Emulation **07/2024 - present**

- Led two RCT emulations and contributed to developing a systematic approach to harness real-world evidence for the evaluation of medication safety and effectiveness in children.
- Evaluated advanced statistical methods (overlap weighting and high-dimensional propensity score approaches) to optimize real-world evidence studies in children.

Peer-Reviewed Publications

- **Lyu N,** Schneeweiss S, Bourgeois F, Savage T. (2025). US Food and Drug Administration Approval of Biologic Drugs for Use in Children and Adolescents, 1965-2024. JAMA Pediatrics. (In-press)
- **Lyu N**, Lin Y, Abughosh S, Rowan P, Varisco T, Chen H. (2025). Prediction of Antipsychotic Associated Weight Gain (AAWG) in Children and adolescents Taking Second Generation Antipsychotics (SGA): A Machine Learning Approach. Journal of Psychiatry Research. (In-press)

- **Lyu N,** Li J, Hutton GJ, Liu X, Aparasu RR. (2025). Comparative effectiveness and safety of glatopa and copaxone in patients with multiple sclerosis. Mult Scler Relat Disord. 2025 Sep 13;104:106750. doi: 10.1016/j.msard.2025.106750. Epub ahead of print. PMID: 40975020.
- **Lyu, N.,** Zahra Majd, Bilqees Fatima, Zhen Zeng, Hua Chen, & Susan Abughosh. (2025). Treatment refractoriness and response rates in patients with relapsed/refractory multiple myeloma: a retrospective analysis of real-world data. Cancer Treatment and Research Communications, 43, 100921.
- **Lyu, N.,** Rowan, P. J., Varisco, T. J., Abughosh, S., Lin, Y., & Chen, H. (2025). Does Concomitant Psychostimulants Mitigate Second-Generation Antipsychotics-Associated Weight Gain? An Observational Study Based on Electronic Medical Records Data. Journal of Child and Adolescent Psychopharmacology. https://doi.org/10.1089/cap.2024.0135
- **Lyu, N.,** Abughosh, S., Varisco, T. J., Lin, Y., Rowan, P. J., & Chen, H. (2024). Group-Based Trajectory Modeling to Identify Patterns of Antipsychotic-Associated Weight Gain Among Children and Adolescents. Journal of Clinical Psychopharmacology, 44(2), 124–132. https://doi.org/10.1097/JCP.0000000000001814
- **Lyu, N**., Rowan, P. J., Abughosh, S., Varisco, T. J., Lin, Y., & Chen, H. (2024). Trajectories and Predictors for the Development of Clinically Significant Weight Gain in Children and Adolescents Prescribed Second-Generation Antipsychotics. Journal of Child and Adolescent Psychopharmacology, 34(4), 21–209. https://doi.org/10.1089/cap.2023.0071
- Chen, H., **Lyu, N**., Calarge, C., Cruz, A. D. L., & Chan, W. (2023). The Effectiveness of Metformin in Managing Second Generation Antipsychotic–Induced Weight Gain in Children and Adolescents. The Journal of Clinical Psychiatry, 85(1). https://doi.org/10.4088/JCP.23m14894
- Zhong, L., Smith, M. L., **Lyu, N.**, Davlasheridze, M., Alonzo, J. P., Lee, S., Wilson, L., & Ory, M. G. (2023). The opioid public health crisis in Texas: Characterizing real-world healthcare resource utilization and economic burden in different clinical settings. Journal of Opioid Management.
- Chen H, **Lyu N**, Chan W, De La Cruz A, Calarge C. (2023). Utilization and Predictors of Adjuvant Metformin in Children and Adolescents on Second-Generation Antipsychotics (Mixed Receptor Antagonists), J Am Acad Child Adolesc Psychiatry. https://doi.org/10.1016/j.jaac.2023.02.017.
- Sanyal S, **Lyu N**, Calarge C, Rowan P, Aparasu R, Abughosh S, Chen H. (2023). Association Between Abnormal Metabolic Parameters and Receiving Subsequent Interventions in Children and Adolescents Initiating Second-Generation Antipsychotics. Journal of Child and Adolescent Psychopharmacology, 2023; 33(7), 269–278. https://doi.org/10.1089/cap.2023.0027
- Huang Y, **Lyu N,** Gohil S, Bapat S, Essien EJ, Thornton JD. (2022). Intention to get naloxone among patients prescribed opioids for chronic pain. Harm Reduct J. 2022;19(1):104. Published 2022 Sep 22. doi:10.1186/s12954-022-00687-5.
- Chen H, Upadhyay N, **Lyu N**, Rowan PJ. (2021). Association of Primary and Behavioral Health Integrated Care Upon Pediatric Mental Disorder Treatment. Acad Pediatr. 2021;21(7):1187-1194. doi:10.1016/j.acap.2021.05.021.

Publications Under Review

- **Lyu N,** Schneeweiss S, Tracy M, Savage T. (2025). Comparative Risk of Infections with Infliximab and Adalimumab in Pediatric Patients with Inflammatory Bowel Disease. JAMA Pediatrics. (Under review)
- **Lyu N**, Li J, Hutton G., Liu X., Aparasu R. (2025). Factors Associated with The Initiation of Glatopa over Copaxone in Patients with Multiple Sclerosis. Journal of Managed Care + Specialty Pharmacy (Revised and resubmitted)

Conference Presentations

- **Lyu N**, Schneeweiss S, Tracy M, Savage T. Comparative Risk of Infections with Infliximab and Adalimumab in Pediatric Patients with Inflammatory Bowel Disease. North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) 2025 Annual Meeting.
- **Lyu N**, Schneeweiss S, Bourgeois F, Savage T. US Food and Drug Administration Approval of Biologic Drugs for Use in Children and Adolescents, 1965-2024. International Society for Pharmacoepidemiology (ISPE) 2025 Annual Meeting (Oral).
- **Lyu N**, Li J, Aparasu R. Factors Associated with Initiating Glatopa Over Copaxone in Multiple Sclerosis. Southern Pharmacy Administration Conference (SPAC) 2025 Annual Meeting.

- **Lyu N**, Li J, Hutton G., Liu X., Aparasu R. Comparative Effectiveness in Multiple Sclerosis Patients Using Generic and Branded Glatiramer Acetate. Academy of Managed Care Pharmacy (AMCP) 2025 Annual Meeting.
- Chen, H, **Lyu, N**. Effectiveness of Psychostimulants on Antipsychotics-Induced Weight Gain in Children. American Academy of Child and Adolescent Psychiatry's (AACAP) 2024 Annual meeting (Oral).
- **Lyu N**, Rowan P, Lin Y, Abughosh S, Varisco T, Chen H. The Effectiveness of Concomitant Psychostimulants in Second Generation Antipsychotics Associated Weight Gain in Children and Adolescents. Academy Health 2024 Annual meeting.
- **Lyu N**, Lin Y, Abughosh S, Rowan P, Varisco T, Chen H. Prediction of Antipsychotic Associated Weight Gain in Children and Adolescents Taking Second Generation Antipsychotics: A Machine Learning Approach. The Professional Society for Health Economics and Outcomes Research (ISPOR) 2024 Annual Meeting.
- Majd Z, **Lyu N**, Chen H, Abughosh S. Treatment refractoriness and response rates in patients with relapsed/refractory multiple myeloma: a retrospective analysis of real-world data. EHA 2023, Germany.
- **Lyu, N.** Abughosh, S. Varisco, T. Lin, Y. Rowan, P. Group-Based Trajectory Modeling to Identify Patterns of Antipsychotic-Induced Weight Gain Among Children and Adolescents. ISPOR 2023 Annual Meeting.
- **Lyu, N.** Chen, H. Impact of PCP Screening on Early Detection of Pediatric Mental Disorder. ISPOR 2021 Annual Meeting.
- **Lyu, N**. Rege, S. Aparasu, R.R. Stimulant and Non-Stimulant Use Among Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD) In Us Ambulatory Visits. Value in Health,23,5,2020. ISPOR 2020 Annual Meeting.
- **Lyu, N**. Rege, S. Aparasu, R.R. ADHD Pharmaceutical Treatments Utilization Among Children and Adolescents In US. WPEC 2020 Annual Conference.
- **Lyu, N.** Sansgiry, S.S. Predictors of Pharmacy Students' Intention to Use Stimulants for Enhancing Academic Performance. 2019 Houston Medication Safety Symposium.
- **Lyu, N.** Sansgiry, S.S. Attitudes and Intention of PharmD Students to Use Stimulants for Enhancing Academic Performance. Value in Health, 22,5,2019. ISPOR 2019 Annual Meeting.

Technical Skills

- ***Statistical Software***: Proficient in the use of statistical software tools commonly employed in HEOR, including Aetion, SAS, STATA, and R.
- ***Economic Modeling Software***: Proficient in utilizing economic modeling software, such as TreeAge Pro and Excel.
- ***Microsoft Office Suite***: Competent in Microsoft Word, PowerPoint, Outlook, and other Microsoft Office applications.