Runqiu(Rachel) Wang

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SUMMARY

Postdoctoral Research Fellow at Boston Children's Hospital & Harvard Medical School; Ph.D. in Biostatistics with 2+ years of industry and FDA regulatory experience. 5+ years applied experience in clinical trial design and execution across Phases I–IV. Expertise in multiple testing/FDR control, survival and longitudinal analysis, adaptive and seamless designs, causal inference and regulatory submissions (CDISC), with 5+ years' experience collaborating across multi-disciplinary teams.

EDUCATION

University of Nebraska Medical Center — **Omaha, NE**
Ph.D. in Biostatistics, GPA: 3.92/4.00 — *August 2021- August 2025*
Thesis: *False discovery rate control in high-dimensional multiple testing.*

Georgetown University — **Washington, DC**
M.S. in Biostatistics, GPA: 3.88/4.00 — *August 2017 - December 2018*
Thesis: *Predictors of time-to-event outcomes in the ALLHAT trial identified with machine learning*.

Hong Kong Baptist University — **Zhuhai, China**
B.S. in Statistics, GPA: 3.30/4.00 — *September 2013 - June 2017*

TECHNICAL SKILLS

Programming Languages:	R, SAS (Certified), Python, MATLAB, C++
Tools:	R shiny, MySQL, UNIX commands for HPC, Parallel computing, AWS
Clinical Trials:	SDTM, ADaM, Define XML, Adaptive Design

WORKING EXPERIENCE

Boston Children's Hospital and Harvard Medical School — **Boston, Massachusetts**
Research Fellow — *August 2025-Presesnt*

- Led sensitivity analyses for the first RCT of Everolimus in PTEN Hamartoma Tumor Syndrome, applying ANCOVA and mixed models to neurocognitive/behavioral endpoints and providing evidence to inform **Phase II design** and regulatory discussions.
- Identifying methodological gaps in **seamless adaptive designs** and developing simulation frameworks to guide innovative trial strategies.
- Exploring **digital twin methodologies** to translate trial findings into real-world patient contexts, with the long-term goal of accelerating drug development and enabling personalized prediction.

U.S. Food and Drug Administration (CDER) — **Silver Spring, Maryland**
ORISE Fellow (Intern) — *May 2024- August 2024*

- Investigated patterns of **missingness** in Ambulatory Blood Pressure Monitoring (ABPM) studies and evaluated statistical methods including Multiple Imputation (**MI**), Inverse Probability Weighting (**IPW**), and Augmented Inverse Probability Weighting (**AIPW**).
- Conducted simulation studies to evaluate and compare the performance of MI, IPW and AIPW under three missing data scenarios: Missing Completely at Random (**MCAR**), Missing at Random (**MAR**) and Missing not at Random (**MNAR**).
- Developed evidence-based recommendations for ABPM study designs by identifying optimal statistical methods based on specific missing data patterns and comprehensive simulation results.

Firma Clinical Research, LLC. — **Hunt Valley, Maryland**
Statistician and SAS programmer — *June 2019–July 2021*

- Led **renal** and **oncology** (solid tumor) studies: prepared statistical analysis plans (**SAP**s), reviewed and contributed to study protocol, designed case report forms (**CRFs**), incorporated adaptive design principles, sample size calculation, hypothesis testing methods and interim analysis strategies.
- Validated and quality-checked statistical analyses and outputs against SAP requirements before submission.
- Contributed to **NDA** submission packages (**Vadadustat**) by developing **ISS/ISE** analyses, **SDTM/ADaM** datasets, and **TFL**s.
- Prepared and validated **Define XML**, **SDRG**, and **ADRG** for inclusion in FDA submissions, ensuring regulatory compliance and consistency across deliverables.
- Communicated and applied statistical knowledge to work with cross-functional teams and external pharma companies.

The Janssen Pharmaceutical Companies of Johnson & Johnson — **Beijing, China**
Statistician (Intern) — *May 2018-August 2018*

- Contributed to an exploratory **real-world evidence** (**RWE**) **safety** analysis of rivaroxaban outcomes in cardiovascular patients, supporting **post-marketing** surveillance and regulatory discussions.
- Applied machine learning methods (lasso, naïve Bayes, classification tree, random forests, gradient boosting) to identify

potential risk factors for adverse events, with a focus on bleeding.
- Developed predictive models achieving at least 85% accuracy, providing insights into high-risk patient subgroups for internal safety evaluations.
- Collaborated with statisticians and clinical researchers to translate preliminary findings into discussion points that informed ongoing safety monitoring and benefit–risk assessment.

RESEARCH EXPERIENCE

University of Nebraska Medical Center **Omaha, Nebraska**

Graduate Research Assistant *August 2021–August 2025*

Dissertation: ***False discovery rate control*** *(FDR) in* ***high-dimensional*** *multiple testing with applications to Alzheimer's disease, oncology biomarkers, and real-world evidence.*

- ***Alzheimer's Disease*** (ADNI study): Created **causal mediation selection** approaches with FDR control to identify MRI biomarkers mediating dementia progression. Results supported mechanistic understanding and potential trial endpoints for early-stage AD.
- ***Oncology Biomarkers*** (WHI study): Developed robust FDR methods for biomarker discovery under **missing/measurement** error, identifying metabolites associated with breast and colorectal cancer. Findings improved reliability of biomarker validation and informed early detection strategies.
- ***EHR*** (N3C COVID-19 Project): Developed **reproducible** statistical methods to detect risk factors from large multi-site EHR data; improved reliability under **heterogeneity** and **missingness**, supporting regulatory-grade real-world evidence generation.
- ***Drug Discovery*** (siRNA/nanocapsule **pre-clinical screening**): Developed multi-layer FDR methods to improve reliability of high-throughput screening, increasing signal detection power by 10% while maintaining **Type-I error** control; supports pre-clinical biomarker and therapeutic target identification.
- ***Nanoparticle Delivery*** (mRNA Tumor Expression): Applied **Bayesian** MCMC and ML (Lasso, RF, XGBoost) to optimize LNP formulations for tumor-targeted expression; identified lipid/particle predictors guiding oncology drug development.

SELECTED PUBLICATIONS

- Wang, R., & Dai, R. (2025). Online multi-layer FDR control. Mathematics, 13(12), 1937.
- Wang, R., Dai, R., Huang, Y., Neuhouser, M. L., Lampe, J., Raftery, D., Tabung, F. K., & Zheng, C. (2025). Variable Selection with FDR Control for Noisy Data – An Application to Screening Metabolites that Are Associated with Breast Cancer and Colorectal Cancer. Journal of Data Science, 23(3), 499-520. doi:10.6339/25-JDS1166.
- Wang, R., Dai, R., Wang, J., Soh, C., Xu, Z., Azzam, M., & Zheng, C. (2025). Model-free High Dimensional Mediator Selection with False Discovery Rate Control. arXiv preprint arXiv:2505.09105.
- Ma, L., Qiao, Y., Wang, R., Chen, H., Liu, G., Xiao, H., & Dai, R. (2024). Machine Learning Models Decoding the Association Between Urinary Stone Diseases and Metabolic Urinary Profiles. *Metabolites*, *14*(12), 674.
- Wang R., Dai, R., Dai, H., & Zheng, C. (2023). Controlling FDR in selecting group-level simultaneous signals from multiple data sources with application to the National Covid Collaborative Cohort data. *arXiv preprint arXiv: 2303.01599*.
- Wang, R., & Peng, X. (2022). Normalized Iterative Hard Thresholding in High Dimensional Logistic Regression With Metagenomics Data. *International Journal of Intelligent Technologies & Applied Statistics*, 15(1).

PRESENTATIONS

- *1st Place of Student Best Poster*, PharmaDS 2025 (Edison, NJ): Mediation Selection with FDR Control for Nonlinear Models.
- *Top-Contributed Paper Presentation*, JSM 2024 (Portland, OR): Variable selection with FDR control for noisy data.
- *Oral-Contributed Talk*, ENAR 2024 (Baltimore, MD): Controlling FDR in selecting group-level simultaneous signals from multiple data sources with application to the National Covid Collaborative Cohort data.
- *Poster*: FDA OB Science Day 2024 (Silver Spring, MD): Missing Data in ABPM Studies.

HONORS and AWARDS

- Selected Fellow, FDA-OCE-ASA Oncology Educational Fellowship (1 of 20 fellows chosen nationwide) 2025–2026
- **1st** Place of Student Best Poster Award at PharmaDS conference, NJ 2025
- UNMC Travel Fellowship (2024 JSM; 2024 ENAR; 2025 PharmaDS) 2024
- Oak Ridge Institute of Science and Education (ORISE) Fellowship at **FDA** 2024

LEADERSHIP & SERVICE

Mentor & Instructor, Oncology Trial Design Workshop Program 2025-Present

- Led student project to build an interactive tool translating SAP/CRF requirements into CDISC-compliant outputs for oncology trial design.

PROFESSIONAL MEMBERSHIPS

American Statistical Association (ASA) Member, Eastern North American Region (ENAR) Member