Alexander S. Perlmutter, PhD, MPH

Curriculum vitae

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Personal   Work
alexander.perlmutter@gmail.com   aperlmut@amgen.com
+1 703 336 9067   +1 347 751 2605

Experience

2024-	Observational Research Manager, Amgen Manager: Min Kim, Director of Observational Research Remote (Denver, CO)

- Post-marketing requirement (PMR): designed pharmacoepidemiological studies that generated real-world evidence (RWE) about the safety profile of latest generation bone health product
  - Leading design and authored protocol/statistical analysis plan (SAP) of negative control outcomes (NCO) study using Medicare and Optum claims databases to support treatment group comparability for eventual noninterventional comparative safety study
  - Led development of a clean-room gating framework and drafted reviewer guidance with quantitative domain-level assessment of unmeasured confounding, strengthening scientific integrity for future NCO and comparative safety work
  - Led design and authored protocol/SAP of the FDA PMR final report, including complex analyses, interpretation, and regulatory-facing recommendations aligned with Amgen/bone franchise strategy
  - Led design and protocol/SAP development for the validation study of 3-point MACE and cardiovascular mortality algorithms using Medicare–REGARDS linked data, confirming feasibility of claims-based outcome definitions for the planned noninterventional comparative safety study
  - Initiated and executed several ad-hoc analyses integrating biometric EHR data into claims using multiple imputation and a transportability framework, empirically demonstrating negligible unmeasured confounding from EHR-only variables in PMR final report data
  - Conducted simulation analyses to quantify direction and magnitude of bias due to nondifferential outcome misclassification and applied validation-based adjustments to understand precision loss when recovering "true" effects
  - Authored multiple regulatory briefing documents and question responses, ensuring clarity, methodological precision, and alignment with FDA expectations

- Additional contributions across regulatory, methodological, and cross-functional initiatives
  - Co-led effectiveness NCO study development and co-authored protocol, negotiating key design elements (washouts, cohort identification period, baseline

control of NCOs), harmonizing processes with safety NCO study, and adding two new NCOs (breast cancer screening, preventive dermatology)
- o Supported global regulatory needs through regulator-mandated analyses for potential safety signals, coordinating U.S. and Japan analyses under shifting priorities and identifying methodological efficiencies across regions
- o Contributed to Japan PMO/MOP program through protocol review, feasibility analyses, and creation of an R Shiny app that automated and accelerated power/sample size calculations across superiority, noninferiority, and equivalence designs
- o Authored key sections of two briefing documents for regulator explaining regulator's study's null safety finding could not be explained away by nondifferential outcome misclassification or treatment groups becoming more similar due to differential attrition
- o Managed TA Bone Team's publication efforts by coauthoring **two manuscripts** (hip/knee arthroplasty; spine surgery) and aligning dissemination strategy with GPPT and cross-functional stakeholders
- o Evaluated PCORNet site performance in terms of Amgen medication users and completeness of biometric and office-based measures unavailable in claims data to optimize feasibility and data quality for future claims–EHR linked analyses
- o Served as an internal study protocol governance body reviewer, presenting one protocol and reviewing **multiple** others, enhancing cross-functional scientific governance and communication

2022-2024	Senior Epidemiologist, Target RWE Manager: Julia Ward, Director of Epidemiology Remote (New York, NY)

- Epidemiology lead on hepatocellular carcinoma (HCC) project using Target-HCC community medical records and questionnaire data
  - o Drafted protocol to study adult patients newly diagnosed with HCC in the United States, specifically:
    - To describe patient demographic, clinical, and disease characteristics
    - To examine trends over time in the distribution of race/ethnicity and viral/non-viral etiology
  - o Compiled codelists for most elements needed for data analysis

- Epidemiology contributor on the Camellia Cohort – an R01-funded longitudinal study to understand sexual health and prevention among women in Alabama.
  - o Built a flexible and automated enrollment monitoring framework in R Markdown that extracted real-world survey data from REDCap via an API and integrated them with data on women with sexually transmitted infections from the Alabama Department of Public Health (ADPH). The framework:
    - Summarized the flow of participants from entry into the ADPH data through eligibility for sampling, sampling, prescreening, STI screening, eligibility for enrollment, and full enrollment via consort-style diagram.
    - Tabularly summarized descriptive data of women at each inclusion stage of the consort-style participant flow diagram.
    - Tabularly summarized enrollees' descriptive data obtained from surveys and ADPH overall and by each of Alabama's eight public health districts.

- Summarized participants' cumulative and biweekly enrollment over time from the first enrollment within each of eight public health districts.
- Summarized the cumulative number of enrollees over each of four planned sampling rounds in maps of 642 Alabama Zip Code Tabulation Areas (one Alabama map per sampling round).
- Summarized the proportion of enrollees who were from Low HIV testing areas, of Black/Other race/ethnicity, and from non-metropolitan Zip Code Tabulation Areas in maps (one map for each characteristic) across eight Alabama public health districts.

- Epidemiology lead on high-risk non-muscle-invasive bladder cancer (HR NMIBC) project using medical records and Komodo claims data
  - Conducted descriptive and survival analyses in R on Komodo cloud environment using linked electronic medical records and Komodo claims data.
  - Wrote protocol for submission to client and statistical analysis plan for assessing descriptive statistics, treatment patterns, and incidence and survival outcomes.
  - Compiled codelists for all elements from both data sources needed to produce variable specification file.
  - Produced variable specification file, which included operationalizations and source data.
  - Drafted abstract for the conference of The Professional Society for Health Economics and Outcomes Research (formerly ISPOR).

- Epidemiology lead on advanced non-small cell lung cancer (advNSCLC) project using real-world Flatiron Health data.
  - Designed study of overall survival following entry into care for advNSCLC and initiation of first- through fourth-line therapy, which featured over 40 planned subgroup analyses (e.g., index date, treatment category, sociodemographics, ECOG, smoking history, positive biomarkers, etc.).
  - Implemented staged plan to continuously refresh study as new data is recorded, update baseline windows for ECOG and calendar period comparisons, and stratify analyses by entry into care definition (diagnosis date vs. first structured activity).
  - Wrote original draft of executive summary and revision when data were refreshed.
  - Presented findings to client via videoconference every one to three months using proprietary population health report interface.

- Epidemiology lead on community insights and biorepository integration projects
  - Built cohorts for each of hidradenitis suppurativa, atopic dermatitis, and irritable bowel syndrome using real-world clinical data.
  - Developed statistical analysis plans based upon queries from industry partners.
  - Evaluated descriptive characteristics, disease progression, treatment patterns, and biospecimens.
  - Oversaw and quality checked summer intern's analysis on nonalcoholic steatohepatitis and dermatology data.

- Epidemiology lead on warm autoimmune hemolytic anemia project
  - Redrafted previously written epidemiology report based on clinical, regulatory, and business development input.

- o Developed research protocol to study rare disease that could serve as external control for regulatory submission of investigational new drug.

- Proposal-writing
  - o Drafted parts of successful proposal to study the treatment of patients with seizures.
    - Contributed to subproposals on 1) real-world effectiveness of antiseizure medication doses and dose titrations on the occurrence of new seizures and hospitalizations, and 2) real-world effectiveness of a newly marketed antiseizure medication on outcomes in the context of historically available antiseizure medications.
  - o Drafted parts of successful proposal to study real-world treatment patterns, clinical outcomes, healthcare resource use and costs in patients with incurable/non-metastatic hepatocellular carcinoma.
    - Contributed to objectives on overall survival and progression-free survival, time to progression, and time to next treatment following initiation of transarterial chemoembolization (TACE) in intermediate stage TARGET-HCC patients.

Education

2017-2023	PhD in Epidemiology, Columbia University Dissertation sponsor: Kara Rudolph, PhD Dissertation title: Examining vaping's possible unintended consequences on cannabis and other substance initiation Mailman School of Public Health New York, NY
2016-2020	Trainee/Researcher, Université Paris Descartes, METHODS Team, Centre de Recherche d'Épidémiologie et Statistiques Paris, France
2014-2016	MPH in Epidemiology, Columbia University Mailman School of Public Health New York, NY

Research Support

5T32DA031099-03:
Epidemiology of Substance Use Disorders Training Program at Columbia University
Principal Investigators: Hasin, Deborah S.; Martins, Silvia M.
Columbia University
New York, NY, United States

Publications

Peer-reviewed articles

1. **Perlmutter AS**, Keyes KM, Giovenco D, Martins SS, Rudolph KE. Is nicotine vaping associated with subsequent initiation of cannabis and other substances from adolescence into young adulthood? Am J Epidemiol. 2024 Jul 10:kwae189. doi: 10.1093/aje/kwae189. Epub ahead of print. PMID: 38988255.

2. Gutkind S, Askari M, **Perlmutter AS**, Nesoff E, Mauro PM, Martins SM. Associations between relative deprivation with opioid use among working-age adults during the great recession. *J. Psychiatr. Res.* 2023;160. doi:10.1016/j.jpsychires.2023.02.010

3. Mielenz TJ, Tian J, Silverman KD, Whalen AM, Kannoth S, Durbin LL, **Perlmutter AS**, Xue QL. The association of pain levels and physical inactivity among older women. *Geriatrics*. 2021;6(103). doi:10.3390/geriatrics6040103

4. **Perlmutter AS**, Benchoufi M, Ravaud P, Tran VT. Identification of patient perceptions that can affect the uptake of interventions using Biometric Monitoring Devices: a systematic review of randomized controlled trials. *J Med Internet Res.* 2020;22:9. doi:10.2196/18986

5. **Perlmutter AS**, Rivera-Aguirre AE, Mauro PM, et al. Sex differences in nonmedical prescription tranquilizer and stimulant use trends among secondary school students in Argentina, Chile, and Uruguay. *Drug Alcohol Depend*. 2019;205:107607. doi:10.1016/j.drugalcdep.2019.107607

6. Mauro PM, Santaella-Tenorio J, **Perlmutter AS**, Hasin DS, Mauro CM, Martins SS (2018). Correct knowledge of medical cannabis legal status in one's own state: Differences between adolescents and adults in the United States, 2004–2013. *Addict. Behav.*;88:23-8. doi:10.1016/j.addbeh.2018.07.021

7. Martins SS, Segura LE, Santaella-Tenorio J, **Perlmutter AS**, Fenton MC, Cerda M, Keyes KM, Ghandour LA, Storr CL, Hasin DS (2017) Prescription opioid use disorder and heroin use among 12-34-year-olds in the United States from 2002 to 2014. *Addict behav*.; 65:236-241. doi:10.1016/j.addbeh.2016.08.033

8. **Perlmutter AS**, Tran VT, Dechartres A, Ravaud P (2016) Comparison of primary outcomes in protocols, public clinical-trial registries and publications: the example of oncology trials. *Ann Oncol* 1;28(4):688-695. doi:10.1093/annonc/mdw682

9. **Perlmutter AS**, Conner SC, Savone M, Kim JH, Segura LE, Martins SS (2016) Is employment status in adults over 25 years old associated with nonmedical prescription opioid and stimulant use? *Soc Psychiatry Psychiatr Epidemiol*;52(3):291-298. doi:10.1007/s00127-016-1312-6

Book Chapters

1. Chen L-Y, **Perlmutter AS**, Segura L, Santaella-Tenorio J, Schleimer JP, Mendez M, et al. Nonmedical Prescription Drug Use in Adolescents and Young Adults. The

Prescription Drug Abuse Epidemic: Incidence, Treatment, Prevention, and Policy. Santa Barbara: ABC-CLIO; 2018. p. 83-114.

Review Papers

1. **Perlmutter AS**, Bauman M, Mantha S, Segura LE, Ghandour L, Martins SS (2018) Nonmedical Prescription Drug Use Among Adolescents: Global Epidemiological Evidence for Prevention, Assessment, Diagnosis, and Treatment. *Curr Addict Rep* 5(2):120-7.
doi:10.1007/s40429-018-0194-y.

In Preparation/Under Review

1. **Perlmutter AS**, Yoon L, Chien S, Brunetti V, Cheng A, Kent S, Lash T, Brookhart AM, Hernandez R, Kim M. Evaluating potential residual noncomparability of Evenity and other osteoporosis treatment groups using negative control outcomes to support the conduct of a noninterventional comparative safety study. [in preparation]

2. Yoon L, **Perlmutter AS**, Chien HC, Brunetti V, Cheng A, Kent S, Lash T, Brookhart AM, Hernandez R, Kim M. Evaluating potential residual noncomparability of Evenity and other osteoporosis treatment groups using negative control outcomes to support the conduct of a noninterventional comparative effectiveness study. [in preparation]

3. **Perlmutter AS**, Chien HC, Xie F, Curtis J, Kim M, Muntner P. Validation of algorithms to identify cardiovascular mortality and 3-point major adverse cardiovascular events in a population of postmenopausal osteoporosis in Medicare claims data. [in preparation]

4. **Perlmutter AS**, Chien HC, Kim M, Lash T. Simulating potential information bias and impact of probabilistic bias adjustment on precision in a noninterventional comparative safety study. [in preparation]

5. **Perlmutter AS**, Chien HC, Raupp D, Narapareddy P, Shannon K, Kim M. Adjusting for potential unmeasured confounding in claims databases using information only available in claims-EHR linked databases using multiple imputation and a transportability framework. [in preparation]

6. Ma, J, Lin TC, Gong T, Chien HC, Golladay GJ, Kates SL, Brady C, Lane JM, Jeray KJ, **Perlmutter AS**, Oates MK, Li X, Liu J. Association of Osteoporosis and Postoperative Outcomes Among Postmenopausal Women who Underwent Elective Hip or Knee Arthroplasty: A Retrospective Cohort Study Based on Medicare Database in the United States. *Journal of Bone & Joint Surgery: American* (under review)

7. Ma, J, Lin TC, Gong T, Chien HC, Freedman BA, Daniels AH, Mitsunaga K, Berven SH, Dimar J, Pinter ZW, **Perlmutter AS**, Oates MK, Li X, Liu J. Osteoporosis Status and PostOperative Patient Outcomes Among Postmenopausal Women Who Underwent Elective Spinal Fusion Surgery: A Retrospective Cohort Study. *Ostoeporosis International* (under review)

Invited Talks

2024	Standardization of a claims-EHR linked population to a claims-only population to investigate potential unmeasured confounding in a claims-only comparative safety study. Amgen CfOR Methods Council. Thousand Oaks, California.
2022	Examining vaping's possible unintended consequences on cannabis and prohibited substance initiation. American Psychopathological Association. New York, New York.
2018	Sex differences in nonmedical prescription tranquilizer and stimulant use among secondary school students in Argentina, Chile, and Uruguay. Society for Epidemiologic Research. Baltimore, Maryland.

Conference Presentations

2026	Validation of a Cardiovascular Mortality Algorithm and Three-Point MACE Among Women with Postmenopausal Osteoporosis. ICPE—International Conference for Pharmacoepidemiology. Milan, Italy.
2026	The Impact of Outcome Misclassification When Evaluating the Real-World Safety of Medicines. ICPE—International Conference for Pharmacoepidemiology. Milan, Italy.
2026	Fit-for-Purpose Evaluation of Claims and Claims-EHR Linked Databases: Accounting for Potential Unmeasured Confounding in a Cardiovascular Safety Study. ICPE—International Conference for Pharmacoepidemiology. Milan, Italy.
2024	Assessing the Value of Linking Abstracted Medical Record Data with Administrative Claims Data to Study Patients with High-Risk Non-Muscle Invasive Bladder Cancer in the United States. ISPOR—The Professional Society for Health Economics and Outcomes Research. Atlanta, Georgia.
2020	Do asthma emergency department visits depend on electronic smoking device availability in California counties from 2013 to 2016? Society for Epidemiologic Research. Online.
2020	Do asthma emergency department visits depend on electronic smoking device availability in California counties from 2013 to 2016? American Psychopathological Association. New York, New York.
2020	The association between prescription opioid misuse and suicidality in United States adolescents: NSDUH 2015-2017. American Psychopathological Association. New York, New York.
2019	Assessment of patient perceptions of interventions using biometric monitoring devices in randomized controlled trials: a systematic review. Society for Epidemiologic Research. Minneapolis, Minnesota.

2019	Nonmedical prescription opioid Use, heroin use, and cardiovascular disease. Society for Epidemiologic Research. Minneapolis, Minnesota.
2019	Medical marijuana use and trouble with the law: Does living in a state with a medical marijuana law modify the relationship? College on Problems of Drug Dependence. San Antonio, Texas.
2018	Sex differences in nonmedical prescription tranquilizer and stimulant use among secondary school students in Argentina, Chile, and Uruguay. College on Problems of Drug Dependence. San Diego, California.
2017	Associations between past-year marijuana use, arrests, and race/ethnicity among 18-49-year-olds in the United States, 2002-2015. College on Problems of Drug Dependence. Montreal, Quebec.
2015	Is employment status in adults over 25 years old associated with nonmedical prescription opioid and stimulant use? Association for Medical Education and Research in Substance Abuse, Washington, D.C.

Journal reviewer

2021-	Drug and Alcohol Dependence 2 review completed
2020-	Journal of Studies on Alcohol and Drugs 2 reviews completed
2020-	Journal of Drug Issues 1 review completed

Conference award

2019	3rd Place Poster Assessment of patient perceptions of interventions using biometric monitoring devices in randomized controlled trials: a systematic review. Society for Epidemiologic Research. Minneapolis, Minnesota. Publication: doi:10.2196/18986

Fellowship awards

2017-present	5T32DA031099-03: Epidemiology of Substance Use Disorders Training Program PI: Hasin, Deborah S. Columbia University, New York, NY, United States
2016-2017	Cofund INSPIRE – European Union Horizon 2020 Marie Skłodowska-Curie Action Université Paris Diderot, Paris, France

Academic research positions

2021	Research assistant, Causal inference course preparation. Rudolph, Kara. Columbia University, New York, NY
2019-2020	Research assistant, Grant proposal preparation. PI: Martins, Silvia. Columbia University, New York, NY
2018	Research assistant, Longitudinal Research on Older Adult Drivers (LongROAD), AAA. PI: Li, Guohua, Supervisor: Thelma Mielenz. Columbia University, New York, NY
2018	Research assistant, Publication preparation for aging and pain research project, Supervisor: Thelma Mielenz. Columbia University, New York, NY
2017-2019	Research assistant, Health and social consequences of national marijuana legalization, 1R01DA040924-01A1. PI: Cerda, Magdalena. University of California Davis, Davis, CA
2016-2018	Research assistant, State medical marijuana laws and NSDUH marijuana use and consequences since 2004, 5R01DA037866-04. PI: Martins, Silvia. Columbia University, New York, NY
2015-2016	Research coordinator, World Trade Center Heart Study, 1U01-OH010722-01. Co-PIs: Morabia, Alfredo; Desvarieux, Moise. CUNY – Queens College, New York, NY