

# NIROSHA M. LEDERER, PHD, MSPH

I am a dynamic policy expert, and health outcomes/economics researcher, and academic with a proven track record of developing innovative strategies to advance value-based healthcare decision-making by both domestic and international agencies including CMS, FDA, state health agencies, commercial payers, HTAs, guideline developers, and patients. With over 15 years of policy, political, and research experience from across the healthcare ecosystem including at FDA, biopharmaceutical industry, consulting, academia, and Capitol Hill, I have a deep understanding of the challenges facing our healthcare system today. As a distinguished and sought-after public speaker, I specialize in analyzing intricate healthcare trends, articulating the role of evidence in determining the pricing and reimbursement of medical products, and designing innovative patient-centered access medical product models (e.g., outcomes-based contracts for transformative therapies). I strive to achieve a high-quality, affordable, accessible, and equitable healthcare system.

## EDUCATION

**UNIVERSITY OF NORTH CAROLINA ESHELMAN SCHOOL OF PHARMACY**, Chapel Hill, NC  
Doctor of Philosophy in Pharmaceutical Outcomes & Policy, May 2018

Doctoral Dissertation: “Optimizing Antiemetic Use to Prevent Chemotherapy Induced Nausea and Vomiting: Lessons Learned with Big Data and Modeling.” Committee Members: Drs. Stacie Dusetzina (Chair), Joel Farley, Stephanie Wheeler, Amber Proctor, and Ethan Basch.

**JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH**, Baltimore, MD  
Master of Science in Public Health in Health Policy, May 2012

**JOHNS HOPKINS UNIVERSITY**, Baltimore, MD  
Bachelor of Arts in Public Health, May 2009

## PROFESSIONAL EXPERIENCE

**Executive Director/Head**, *Policy Evidence*, AstraZeneca, Gaithersburg, MD, Apr 2024 – Current

- Collaborate with external experts spanning academia, industry, scientific societies, governments, NGOs, tech companies, and ecosystem builders to build resilient and sustainable healthcare systems around the world
- Lead the design, commissioning, and oversight of evidence generation for priority policy programs
- Publish and present evidence in relevant external journals and meetings
- Develop global framework to support evidence generation for policy across AstraZeneca
- Build AstraZeneca’s health policy evidence generation capabilities

**Vice President**, Strategic Selling and **Head**, *US Federal Government*, Aetion Inc., New York, NY. Jan 2024-Apr 2024

**Vice President & Head**, *US Federal Government*, Aetion Inc., New York, NY. Sep 2023-Jan 2024

**Senior Director & Head**, *US Government Partnerships*, Aetion Inc., New York, NY. Mar 2022-Aug 2023

**Director**, *Real World Evidence Strategy*, Oct 2020-Feb 2022

- Established and served as the inaugural head of Aetion’s US Federal Government business including development of commercial, operations, and delivery functions
- Oversee US Federal Government (e.g., FDA, CDC, CMMI, and NIH) accounts and serve as senior relationship manager
- Advise company on legislative and regulatory strategies regarding policies on Real World Data (RWD) and RWE including serving as key liaison with think tanks and the trade organizations (e.g., RWE Alliance)
- Spearheaded the development and execution of go-to-market strategies for US Federal government; exceeded financial targets in 2021 and 2022

- Scope, establish, and manage external channel partnerships with IT governments contractors and data partners
- Consult with biopharmaceutical and MD&D clients on regulatory and payer engagement and negotiation strategies using RWD and RWE, with a focus on high-cost, specialty products

**Assistant Director/Managing Associate, *Real World Evidence, Margolis Center for Health Policy***, Duke University, Durham, NC, Mar 2019-Oct 2020

- Developed strategic partnerships with domestic and international thought leaders and C-suite executives representing government, payers, physicians, patients, data vendors, and academics to identify emergent issues on as well as create and implement policies regarding real world data capture and analysis for FDA and CMS
- Led RWE Collaborative, a multi-stakeholder group of C-suite leaders representing sponsors, researchers, payers, data companies, and patients on regulatory use of real-world evidence
- Oversaw four-person team to execute on research agenda including workshop hosting, white paper development, and stakeholder engagement
- Served as primary investigator on Building Capacity for Patient Engagement in Real-World Evidence Development (PCORI Engagement Award Project)
- Managed P&L for responsibilities and strategic planning for Center's real-world evidence portfolio

**Subject Matter Expert, *Patient-Focused Drug Development, Oncology Center of Excellence***, US Food and Drug Administration, Washington DC, Sep 2018-Jul 2019

- Created and validated standards on capturing, analyzing, and communicating patient-reported outcomes in oncology
- Developed guidance on incorporation of PROs into oncology clinical trial design
- Managed technical advice and communications on clinical outcomes assessments in oncology with domestic and international healthcare regulators and payers (e.g., FDA-CMS Memorandum of Understanding)

**Fellow, *Value-Based Payment, Margolis Center for Health Policy***, Duke University, Durham, NC, Jul 2017-Jun 2018

- Conducted landscape analysis and developed white paper on value-based oncology payment models
- Analyzed survey data on value-based agreements and lead manuscript development summarizing key results and recommendations

**BMS-UNC Pre-Doctoral Fellow, *Worldwide Health Economics and Outcomes Research***, Bristol-Myers Squibb, Princeton, NJ, Jul 2016-Jun 2018

- Created payer (US commercial, Medicare, and global HTA) evidence-generation strategies (including clinical and economic, cost-effectiveness, and epidemiology studies) to support inline and pipeline immunoscience portfolio

**MBA Intern, *Marketing Science***, Genentech, South San Francisco, CA, Jun 2015-Aug 2015

- Developed and executed a large database analysis to characterize patient populations and for sales force targeting for multiple sclerosis
- Generated strategic business insights to inform forecast implication scenarios for product launch

**Manager, *Evidence-Based Medicine Policy / Health Economics and Outcomes Research***, Avalere Health LLC, Washington, DC, Jun 2011-Jul 2014

- Provided strategic support to senior leadership in industry, professional societies, and patient organizations on how to implement and respond to new and existing federal legislation and regulation (e.g., crafting legislative strategies, developing comment letters, and engaging key stakeholders)
- Analyzed federal healthcare policy related to value-based care, real-world evidence, patient-focused drug development, and patient-centered outcomes research to identify implications on healthcare clients in the private and public sectors
- Organized and executed site visits as well as collected and analyzed data for the evaluation of the Center for Medicare and Medicaid Innovation's Accountable Care Organization program

- Conducted comprehensive and systematic therapeutic-specific evidence landscape assessments that spanned trial data, clinical literature, economic reviews, patient-reported outcomes, global health technology assessments, and quality measures to identify marketplace threats and opportunities
- Developed US and ex-US payer and medical value messages as well as created HEOR tactical plans and evidence generation strategies to support new product launches
- Facilitated day-to-day project activities including leading mixed level teams, managing budgeting, and serving as the client point-of-contact across market access and HEOR work streams
- Monitored, evaluated, and briefed clients on trends related to the Agency for Healthcare Research and Quality, Food and Drug Administration, Centers for Medicare & Medicaid Services, and the Patient-Centered Outcomes Research Institute

### **LEGISLATIVE AND STATE GOVERNMENT EXPERIENCE**

**Policy Intern**, *Committee on Ways and Means, Subcommittee on Health*, U.S. House of Representatives, Washington, DC, Jan 2010-Jun 2010

- Assisted staff with developing briefing materials and providing research to inform hearings during the development of the 2010 Affordable Care Act
- Provided responses to healthcare reform inquiries from Congressional members and the public

**Legislative Intern**, *Office of Congressman Eliot Engel (NY-17)*, U.S. House of Representatives, Washington, DC, Jan 2009-Jun 2009

- Aided legislative staff with research projects
- Wrote constituent correspondence, led Capitol tours, provided administrative assistance

**Health Advocacy Specialist**, Office of the Maryland Attorney General, Baltimore, MD, Jun 2008

- Mediated between clients and health insurance companies
- Advised clients on how to proceed with their complaints

### **ACADEMIC & CLINICAL RESEARCH EXPERIENCE**

**Adjunct Assistant Professor**, *Division of Pharmaceutical Outcomes and Policy*, University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC, February 2024-Current

- Provide guest lecturer and seminars
- Mentor and provide research training to doctoral and postdoctoral students
- Advise on Division's Strategic Plan

**Graduate Student Research Assistant**, *Division of Pharmaceutical Outcomes and Policy*, University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC, Aug 2014-Jun 2016

- Conducted disease-specific literature reviews
- Supported claims database analyses

**Graduate Student Research Assistant**, *Department of Health Policy & Management and Department of Epidemiology*, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, Jul 2010-Jun 2011

- Identified extensive list of key search terms to inform a systematic review on how researchers are using internal company documents
- Developed search terms database and search strategy for atypical topics in subject specific databases

**Research Coordinator**, *Department of International Health Center for Human Nutrition*, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, May 2010-Dec 2010

- Executed data management strategies for qualitative research including overseeing survey data collection, database entry, and software analysis
- Managed project aims and coordinated events with the community
- Trained and supervised 15 students with data collection through survey and data entry

**Research Assistant**, *Department of Gastroenterology*, Johns Hopkins Hospital / School of Medicine Baltimore, MD, 2006-2009

- Coordinated study to investigate the effects of smoking on Ulcerative Colitis through a retrospective cohort study funded by the American Gastroenterological Association Student Research Fellowship
- Created original study plan, chart review, and information database
- Compiled and analyzed chart data

## MANUSCRIPTS

- Oehrlein EM, Love TR, Burke L, Calvert M, Schoch S, **Mahendraratnam N**, Peretto EM. “Patient-Centered Outcomes Are Not Always Patient-Reported Outcomes: An Introduction and Framework to Quell the Confusion.” *Value Health (Under Review)*.
- **Lederer (Mahendraratnam) N** & Arad N. “Unlocking Future Healthcare Insights: Seize the Opportunity by Investing in RWD/RWE Today.” *Health Affairs Forefront. (In Press)*.
- King-Kallimanis B, Cell D, Calvert M, Cocks K, Coehn C, Fairclough D, Howie L, Jonsson P, **Mahendraratnam N**, Mahues J, Sarac S, Sasseville M, Shaw J, Stigger N, Trask P, Wieseler B. “Perspectives on Patient-Reported Outcome Data After Treatment Discontinuation in Cancer Clinical Trials.” *Value Health*. 2023 Jul 6;S1098-3015(23)03036-X.
- **Lederer (Mahendraratnam) N** & Sharma Y. “The power of AI begins with the data.” *Future Medicine AI Hub*. 13 June 2023.
- Rivera SC, Aiyegbusi OL, Ives J, Draper H, Mercierca-Bebger R, Ells C, Hunn A, Scott JA, Fernandez CV, Dickens AP, Anderson N, Bhatnagar V, Bottomley A, Campbell L, Collett C, Collis P, Craig K, Davies H, Golub R, Gosden L, Gnanasakthy A, DAVIES EH, von Hilderbran M, **Mahendraratnam N**, Lord JM, Miyaji T, More T, Monteiro J, Zwisler AO, Peipert JD, Roydhouse J, Stover AM, Wilson R, Yap C, Calvert MJ. “Ethical considerations for the inclusion of patient-reported outcomes in clinical research: The PRO ethics guideline.” *JAMA*. 2022 May 17;327(19):1910-1919.
- Stern AD, Bronneke J, Hagen J, Matthies H, Patel S, Clay I, Debatin J, Herr A, Hoeller K, Jaksa A, Kramer DB, Kyhlstedt M, Lofgren KT, **Mahendrarantam N**, Muehlan H, Reif S, Ridermann L, Goldsack J. “Advancing Digital Health Applications: Priorities for Innovation in Real-world Evidence Generation.” *Lancet Digit Health*. 2022 Mar;4(3):e200-e206.
- King-Kallimanis BL, (Lederer) **Mahendraratnam N**, Kim J, Nair A, Horodniceanu E, Bhatnager V, and Kluetz PG. “Characterization of Patient-Reported Outcome Follow-up Data in Breast, Prostate, Hepatocellular Carcinoma and Pancreatic Cancer Clinical Trials Following Treatment Discontinuation.” *Value Health*. 2021 Sep;24(9):1302-1307.
- Jaksa A & **Mahendraratnam N**. “Learning from the Past to Advance Tomorrow’s Real World Evidence: What Demonstration Projects Have to Teach Us.” *J Comp Eff Res*. 2021 Sep 14.
- **Lederer (Mahendraratnam) N** & Dusetzina S. “Accelerated Approval – An Unexpected Pathway to Value-based Pricing?” Health Affairs Blog. August 2021. 10.1377/hblog20210812.337699
- Kaufman BG, Whitaker R, **Mahendraratnam N**, Hurewitz S, Yi S, Smith VA, and McClellan M. “Effects of State Social Distancing Policies and Timely Closure on COVID-19 Cases.” *BMC Public Health*. 2021 Jun 28;21(1):1239.
- **Mahendraratnam N**, Mercon K, Gill M, Benzing L, and McClellan M. “Understanding Use of Real-World and Real-World Evidence (RWE) to Support Effectiveness Decisions.” *Clin Pharmacol Ther*. 2021 Apr 23.
- Kaufman BG, **Mahendraratnam N**, Nguyen T, Benzing L, Beliveau J, Silcox C, and Wong CA. “Factors Associated with Initial School Reopening Plans during the COVID-19 Pandemic.” *Gen Intern Med*. 2020 Dec;35(12):3627-3634.
- Kaufman BG, Whitaker R, **Mahendraratnam N**, Smith VA, and McClellan M. Effect of Reopening Non-essential Businesses on COVID-19 Cases in the United States. *Gen Intern Med*. 2020 Oct 6;1-8.
- Orsini LS, Berger M, Crown W, Daniel G, Eichler H, Goettsch W, Graff J, Jonsson P, (Lederer) **Mahendraratnam N**, Monz B, Mullins, CD, Schneeweiss S, Van Brunt D, Wang SV, Guerino J, and Willke RJ. “Improving Transparency to Build Trust in Real-World Secondary Data Studies for Hypothesis Testing—Why, What, and How: Recommendations and a Road Map from the Real-World Evidence Transparency Initiative.” *Value Health*. 2020 Sep;23(9):1128-1136.
- Orsini LS, Berger M, Crown W, Daniel G, Eichler H, Goettsch W, Graff J, Jonsson P, (Lederer) **Mahendraratnam N**, Monz B, Mullins, CD, Schneeweiss S, Van Brunt D, Wang SV, Guerino J, and Willke RJ. “Improving Transparency to Build Trust in Real-World Secondary Data Studies for

Hypothesis Testing—Why, What, and How: Recommendations and a Road Map from the Real-World Evidence Transparency Initiative.” *Pharmacoepidemiol Drug Saf.* 2020 Sep 13.

- Davi R, **Mahendraratnam N**, Chatterjee A, Dawson J, and Sherman R. “Informing Single-Arm Clinical Trials with External Controls.” *Nat Rev Drug Discov.* 2020 Aug 8;19(8).
- **Mahendraratnam N**, Farley JF, Basch EM, Proctor A, SB Wheeler, and Dusetzina SB. “Patterns and Predictors of Antiemetic Use in Patients Initiating Highly Emetogenic Chemotherapy.” *Supportive Care in Cancer.* 2019 Mar 26.
- **Mahendraratnam N**, Sorenson C, Richardson E, Daniel G, Buelt L, Westrich, K, Qian J, Campbell H, McClellan M, and Dubois RW. “Value-Based Agreements May Be More Prevalent Than You Think.” *Am J Manag Care.* 2019 Feb;25(2):70-76.
- **Mahendraratnam N** and Dusetzina SB. “Getting More Value from Outcomes-Based Contracts.” *J Law Med Ethics.* 2018 46(4), 964–966.
- Hansen RA, Hohmann N, Maciejewski ML, Domino ME, Ray N, **Mahendraratnam N**, and Farley JF. “Continuity of Medication Management among Adults with Schizophrenia and Comorbid Cardiometabolic Conditions.” *J Pharm Health Serv Res.* 2018 Mar;9(1):13-20.
- Fang G, Annis IE, Robinson JG, Farley JF, **Mahendraratnam N**, Hickson RP, and Stürmer, T. “Risk Factors for Acute Renal Failure- and Hyperkalemia-Related Hospitalizations among Elderly Patients Taking Angiotensin-Converting Enzyme Inhibitors or Angiotensin II Receptor Blockers after an Acute Myocardial Infarction. *Pharmacotherapy.* 2018 Jan;38(1):29-41.
- **Mahendraratnam N**, Dusetzina SB, and Farley JF. “Prescription Drug Utilization and Reimbursement Increased Following State Medicaid Expansion in 2014.” *J Manag Care Spec Pharm.* 2017 Mar;23(3):355-363.
- Farley JF, Hansen RA, Domino ME, Borse M, **Mahendraratnam N**, Ray N, and Maciejewski ML. “Continuity of Medication Management in Medicaid Patients with Chronic Comorbid Conditions: An Examination by Mental Health Status.” *Gen Hosp Psychiatry.* 2017 Mar - Apr; 45:25-31.
- Erim DO, **Mahendraratnam N**, Okafor P, and Wheeler SB. “The Value of Vedolizumab as Rescue Therapy in Moderate-Severe Crohn's Disease Patients with Adalimumab Non-response in the USA.” *J Crohns Colitis.* 2015 Aug;9(8):669-75.
- Wieland SL, Rutkow L, Vedula SS, Kaufmann CN, Rosman L, Twose C, **Mahendraratnam N**, and Dickersin K. " Who Has Used Company Documents for Biomedical and Public Health Research and Where Did They Find Them?" *PLoS One.* 2014 May 6;9(5).

## WHITE PAPERS

- Mercon K, **Mahendraratnam N**, Eckert J, Silcox C, Romine M, Lallinger K, Kroetsch A, Fazili H, Woskinska M, and McClellan M. “A Roadmap for Developing Study Endpoints in Real-World Settings.” Duke Margolis Center for Health Policy. August 2020.
- **Mahendraratnam N**, Mercon K, Eckert J, Frank K, Romine M, Kroetsch A, Sherman R, Daniel G, and McClellan M. “Adding Real-World Evidence to a Totality of Evidence Approach for Evaluating Marketed Product Effectiveness.” Duke Margolis Center for Health Policy. December 2019.
- **Mahendraratnam N**, Eckert J, Mercon K, Frank K, Romine M, Kroetsch A, Sherman R, Daniel G, and McClellan M. “Understanding the Need for Non-Interventional Studies Using Secondary Data to Generate Real-World Evidence for Regulatory Decision Making, and Demonstrating Their Credibility.” Duke Margolis Center for Health Policy. November 2019.
- **Mahendraratnam N**, Silcox C, Mercon K, Kroetsch A, Romine M, Harrison N, Aten A, Sherman R, Daniel G, and McClellan M. “Determining Real-World Data’s Fitness for Use and the Role of Reliability.” Duke Margolis Center for Health Policy. Oct 2019.
- Democratic Professional Staff. “Employer Responsibility Flowchart.” *House Committee on Ways and Means Subcommittee on Health.* 2010.

## PODIUM PRESENTATIONS

- Mercon K, Eckert J, **Mahendraratnam N**, Kroetsch A, Wosińska ME, and McClellan M. “Understanding Use of Real-World Data (RWD) and Real-World Evidence (RWE) to Support Effectiveness Labeling Changes.” *International Society for Pharmacoeconomics and Outcomes Research Annual Meeting* (2020).

- **Mahendraratnam N**, Dusetzina SB, and Farley JF. “Understanding the Impact of Medicaid Expansion on Prescription Drug Utilization and Spending.” *International Society for Pharmacoeconomics and Outcomes Research Annual Meeting* (2016).
- **Mahendraratnam N**, Inocencio T, Gaffney J, Agatep B, and Hughes KE. “Identifying Recent Trends in Health Technology Assessments for Crohn’s Disease.” *International Society for Pharmacoeconomics and Outcomes Research Annual Meeting* (2014).

### POSTER PRESENTATIONS

- Labban M, Patrick A, **Mahendraratnam N**, Jao R, Patel P, Jaksa A. “The Impact of Value-Based Pricing (VBP) Vs International Reference Pricing (IRP) on Innovative Drugs in the US.” *ISPOR 2022* (2022).
- Kim J, King-Kallimanis BL, **Mahendraratnam N**, Kluetz PG. “Patient-Reported Outcomes in Hematology and Oncology Labels.” *International Society for Pharmacoeconomics and Outcomes Research Annual Meeting* (2019).
- Schneider M, **Mahendraratnam N**, Hamilton-Lopez M, Daniel G, McClellan M. “Assessing the Implementation of Value-Based Payments for Oncology Treatment within the Existing Care Structure.” *Drug Information Association Annual Meeting* (2018).
- Annis IE, **Mahendraratnam N**, Stürmer T, Farley JF, Robinson JG, and Fang G. “Severe Adverse Events and Treatment Discontinuation and Their Risk Factors in Elderly Patients Taking Angiotensin-Converting Enzyme Inhibitors or Angiotensin Receptor Blockers Following AMI.” *32nd International Society for Pharmacoepidemiology* (2016).
- Farley JF, Hansen RA, Domino ME, Ray N, **Mahendraratnam N** and Maciejewski ML. “Continuity of Prescribing and Medication Adherence in Patients with Schizophrenia and Cardiometabolic Comorbidities.” *32nd International Society for Pharmacoepidemiology* (2016).
- **Mahendraratnam N**, Dusetzina SB, and Farley JF. “Understanding the Impact of Medicaid Expansion on Prescription Drug Utilization and Spending.” *Academy Health Annual Research Meeting* (2016).
- Wieland SL, Rutkow L, Vedula SS, Kaufmann CN, Rosman L, Twose C, **Mahendraratnam N**, and Dickersin K. “Who is Using Internal Company Documents for Research and Where Did They Get Them?” *Peer Review Congress* (2013).
- Hanger M, **Mahendraratnam N**, Mitchell K. “Assessing the Evidence Assimilation Time Frame: From Trials to Treatment Guidelines in Cardiovascular Disease.” *International Society for Pharmacoeconomics and Outcomes Research Annual Meeting* (2012).
- Vedula S, **Mahendraratnam N**, Rutkow L, Kaufmann C, Rosman L, Twose C, Dickersin K. “A Snowballing Technique to Ensure Comprehensiveness of Search for Systematic Reviews: A Case Study.” *19<sup>th</sup> Cochrane Colloquium* (2011).
- Graham K, Martins P, Rikoon A, **Mahendraratnam N**, Frick K, Rowan M, Gittelsohn J. “Relationships between Income, Food Expenditures and Purchasing Choices in African American Church Goers in Baltimore City.” *Experimental Biology* (2011).
- Gittelsohn, J, Summers A, Rowan M, Goheer A, Martins P, Graham K, **Mahendraratnam N**. “Healthy Bodies, Healthy Souls: Design of a Church-based Environmental Intervention Program to Prevent Diabetes Risk Behavior.” *Experimental Biology* (2011).
- **Mahendraratnam N**, Hutfless S, Dudley-Brown S, Picco M, Bayless T. “The Patterns of Smoking in Ulcerative Colitis.” *Digestive Disease Week* (2009).
- Munsell M, **Mahendraratnam N**, Bayless T, Dassopoulos T. “Yield of Neoplasia from Biopsies & Chromoendoscopy in Patients Undergoing Colitis Surveillance.” *Digestive Disease Week* (2009).

### INVITED PRESENTATIONS AND CONFERENCE PANELS

- **Mahendraratnam N** (Panel with Sean Tunis, Maria Glymour, and Emily Zeitler). “Medicare Coverage with Evidence Development for Drugs Approved for Alzheimer’s Disease: Which Study Designs and Data Sources Would Best Answer Medicare’s Questions?” *ISPOR 2023* (2023).
- **Mahendraratnam N** (Panel with Micki Tripathi, Michelle Tarver, Yashoda Sharma, and Craig Lipitz). “Workshop Title: Building and Sustaining Diversity & Equity in Digital Health?” *FasterCures* (2023).

- **Mahendraratnam N** (Panel with Marianne Hamilton-Lopez, Margaret Labban, and Lauren Neves). “What Is the Preferred Approach to US Drug Pricing Reforms: International Reference Pricing or Value Based Pricing?” *ISPOR 2022* (2022).
- **Mahendraratnam N** (Panel with Mehmet Burcu, Elisabeth Oehrlein, and Donna Rivera.) “Getting Real with Real World Evidence for Regulatory Decision Making: Where Are We Going?” *ISPOR 2022* (2022).
- **Mahendraratnam N** (Panel with Everett Crosland, David Bates, Elizabeth Anderson, and Barbara Heikens). “Commercializing novel disease-modifying categories.” *Endpoints at JPMorgan* (2022).
- **Mahendraratnam N** (Panel with Jon Fortt, Silas Buchanan, Andy Coravos, Shantanu Nundy, and Micky Tripathi). “Is Digital Health a Bridge to Health Equity.” *FasterCures and the Milken Institute Center for Public Health. Partnering for Patients Forum* (2021).
- **Mahendraratnam N** (Panel with Michelle Tarver, Alice Turnbull, and James Wu). “Who and What Are We Missing in Real-World Data? How Do We Improve the Capture of Social Determinants of Health?” *ISPOR European Meeting* (2021).
- **Mahendraratnam N** (Panel with John Concato, Shirley Wang, Jessica Franklin, Dan Gebremedhin, and Simon Dagenais). “RWE Year in Review.” *DIA Real World Evidence Conference* (2021).
- **Mahendraratnam N** (Panel with Marianne Hamilton-Lopez, Jeff Allen, Robert Sanders, and Brent Rice.) “Value in Cancer Care.” *17th Annual AAADV Workshop* (2021).
- **Mahendraratnam N**. “Democratizing Real-world Patient Centered Outcomes Research.” *National Academies of Sciences, Engineering, and Medicine, Building Data Capacity for Patient-Centered Outcomes Research: An Agenda for 2021 to 2030* (2021).
- **Mahendraratnam N**. “RWE for Demonstrating Drug Effectiveness.” *4th Annual Real World Data & Life Sciences Analytics Congress* (2021).
- **Mahendraratnam N**. (Panel with David Thompson, Lou Fiore, and Lindsay Kehoe). “Should We Be Talking ‘Embedded’ Rather Than ‘Pragmatic’ For Real-world Clinical Trials.” *International Society for Pharmacoeconomics and Outcomes Research Annual Meeting* (2021).
- **Mahendraratnam N**. “Collaborating to Generate Fit-for-Use RWE Post Covid-19.” *SCOPE Virtual Summit for Clinical Ops Executives* (2021).
- **Mahendraratnam N**. “Role of Real-World Evidence in Regulatory Decision-Making Before, During, and After COVID.” *American Course on Drug Development and Regulatory Sciences Webinar Series* (2020).
- **Mahendraratnam N** (Invited Panel with Patrick Loerch, Christopher Boone, and Jeffrey Morgan). “Emerging trends in the expanded use of RWE across the life sciences industry. Where is the industry going?” *SCOPE Webinar Series* (2020).
- **Mahendraratnam N**. “Impact of COVID-19 on the Generation and Use of Real-world Data and Real-world Evidence.” *3rd Annual Real World Data & Life Sciences Analytics Congress* (2020).
- **Mahendraratnam N** (Panel with Jacqueline Corrigan-Curay, Peter Arlett, Pall Jonsson, and Gracie Lieberman). “Pre-competitive Collaborations: Improving Real World Evidence (RWE) Development Efforts in Service of Patients” *DIA Europe* (2020).
- **Mahendraratnam N** (Panel with Edmund Pezalla and Imad Al-Dakkak). “Real World Use of Real World Evidence?” *DIA* (2020).
- **Mahendraratnam N** (Panel with Bart Barefoot, Pall Jonsson, and Alison Bourke). “Moving From Ideas to Action: What is the Role of Global Collaboration.” *International Society for Pharmacoeconomics and Outcomes Research Annual Meeting* (2020).
- **Mahendraratnam N** (Invited Panel with Nicole Mahoney, Aaron Liebttag, and Safiya Karim). “Demonstrating How Real World Data/Evidence Can be Used in Support of Regulatory Approvals.” *Canadian Society for Pharmaceutical Science / Health Canada Workshop on The Use of Real World Data/Evidence and Regulatory Decision Making* (2019).
- **Mahendraratnam N** (Panel with Bart Barefoot, Pall Jonsson, and Lucinda Orsini). “Transparency in RWE - Moving Forward.” *International Society for Pharmacoeconomics and Outcomes Research Annual European Meeting* (2019).
- **Mahendraratnam N**. “Demonstrating Real World Data Reliability to Support Fitness-for-Use.” *2nd Annual Real World Data & Life Sciences Analytics Congress* (2019).
- **Mahendraratnam N**. “Creating Evidentiary Synergies: Leverage RWD for Multi-stakeholder Decision-making.” *3rd Annual TARGET Payer Summit* (2019).

- **Mahendraratnam N** (Invited Panel with Sebastian Schneeweiss, Marc Berger, and Lucinda Orsini). “Transparency in RWE - Time for a Unified Approach.” *International Society for Pharmacoeconomics and Outcomes Research Summit* (2019).
- **Mahendraratnam N**. “Transforming Drug Development through Real-World Evidence.” *Evolution Summit* (2019).

### **PROFESSIONAL SERVICE**

- **Planning Committee Member**, *Real World Evidence Conference*, Drug Information Association, May 2022-Current.
- **Steering Committee Member**, *Digital Health Measurement Collaborative Community*, Digital Medicine Society (DiMe), May 2021-Current.
- **Team Member**, *Practical Approaches for Embedding Trials into Health Care Settings*, Clinical Trials Transformation Initiative, April 2021 - Current.
- **Expert Advisory Panel Member**, *Optum Labs - MRCT Center Observational Patient Evidence for Regulatory Approval and Understanding Disease (OPERAND)*, August 2019 – October 2020.
- **Steering Committee Member**, *RWE Transparency Initiative*, International Society for Pharmacoeconomics and Outcomes Research, March 2019 – October 2020.
- **Member**, *Academy Health 2019 National Health Policy Conference Abstract Review Committee*, AcademyHealth, February 2019.
- **Member**, *18th Annual European Congress Research Abstract Review Committee*, International Society for Pharmacoeconomics and Outcomes Research, June 2015.

### **LEADERSHIP AND VOLUNTEER EXPERIENCE**

**Member**, Hopkins Alumni Representatives Council, Johns Hopkins University, Baltimore, MD, September 2014-Current

- Participate in local undergraduate recruitment activities
- Conduct in-person interviews and provide admission recommendations to the University

**Team Lead**, *2014 Micro-Project*, Compass Strategic Business Consulting, Washington, DC, January 2014-May 2014

- Led three mid-level consultants in creating a successful strategic alignment plan for New Futures, a DC-based non-profit that provides career and scholarship support to low-income young persons
- Developed original Board and staff assessment survey
- Conducted gap analysis and generated recommendations supported by non-profit best-practices

**Pro-bono Consultant**, *2013 Micro-Project*, Compass Strategic Business Consulting, Washington, DC, January 2013-June 2013

- Provided strategic guidance to a Micro-Project that assisted Offender Aid Restoration in creating a successful board development strategy including Board recruitment, training, and maintenance

### **AWARDS AND HONORS**

- ISPOR 21st Annual International Meeting Student Podium Presentation Finalist, 2016
- ISPOR 21st Annual International Meeting Student Travel Grant Awardee, 2016
- UNC Eshelman School of Pharmacy Division Travel Award, 2016
- UNC Eshelman School of Pharmacy Speed Networking Event Champion, 2016
- Biotech 50 Leaders of Tomorrow Summit Representative, 2015
- David A. Winston Health Care Policy Fellowship Semi-Finalist, 2011
- Johns Hopkins University Alumni and Development Staff Retreat Keynote Speaker, 2010
- Dean’s List, Johns Hopkins University, Spring 2009
- Commencement Speaker, Johns Hopkins University, Spring 2009
- American Gastroenterological Association Student Research Fellowship, 2008
- Leroy and Helen Sheats Scholarship Recipient, Johns Hopkins University, 2007-2009
- Charles D. Miller Scholarship Recipient, 2005-2009

### **JOURNAL REVIEWER**



- American Journal of Managed Care
- Health Affairs
- Journal of the American College of Cardiology
- npj Digital Medicine
- Pharmacoepidemiology and Drug Safety
- Value in Health

**Additional Information:** US Citizen, Fluent in English, STATA, SAS, and MS Office