

Engineering & Scientific Consulting

Nathalie Horowicz-Mehler, Ph.D.

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Professional Profile

Nathalie is a solution-focused and resourceful executive with 20+ years of scientific and consulting expertise in HEOR and RWE/RWD applied to clinical innovation.

She has a track record of building and leading high-performing entrepreneurial teams to catalyze innovations in public health, leveraging her clinical expertise and knowledge of multimodal RWD. technology, and advanced analytics.

Nathalie is a frequent public speaker adept at working with internal cross-functional teams and external stakeholders including Life Sciences partners, providers, payers, and regulators.

Academic Credentials & Professional Honors

Ph.D., Epidemiology, Columbia University, 2017

M.S., Pain Research, Education and Policy, Tufts University, 2002

B.S., Behavioral Neuroscience, Lehigh University, 1999

NIH T32 Cancer Training Grant Recipient (2007-2008)

NIH R25 Training Grant Recipient (2005-2006)

Awarded position at the AACR Pathobiology of Cancer Workshop (2007)

Academic Appointments

2006 - 2008

- · Teaching Assistant for Core Epidemiology Courses for Master's and PhD Students. Columbia University
- · Application of Epidemiologic Methods (Applied Statistical Analysis Software (SAS). Helped students elaborate research questions, choose statistical tests, program, and interpret results.
- · Design and Conduct of Observational Epidemiology (Epidemiologic methods). Taught a weekly seminar applying epidemiologic concepts presented in class
- · Principles of Epidemiology III-Analysis (Applied data analysis). Taught a weekly lab. applying statistical methods and associated code presented in-class

Prior Experience

ConcertAl | Cambridge, MA Senior Vice President, General Manager 01/2021-06/2023

IQVIA | New York, NY Vice President, Practice Leader 01/2017-01/2021

Quintiles | New York, NY Senior Director-Principal 01/2008-01/2017

Mapi Values LLC | Boston, MA Project Manager, Health Outcomes 01/2002-01/2005

Publications

Dreyer N, Horowicz-Mehler N. Use of RWE in Clinical Development to Enhance Regulatory Submissions: Complementary innovative trial designs can enrich randomized control trial data. White Paper published July 2020; Sponsored by IQVIA and Applied Clinical Trials.

Kotak S, Mardekian J, Horowicz-Mehler N, Shah A, Burgess A, Kim J, Gemmen E, Boyd H, Koenig A. Impact of Etanercept Therapy on Disease Activity and Health-related Quality of Life in Moderate Rheumatoid Arthritis Patients: Population from a National British Observational Cohort. September/October 2015 issue of Value in Health

Doyle J, Horowicz-Mehler N. A CRO's Role in Driving Development to Match Market Demands. Patient's Week. PM360. Published October, 2011.

Doyle J, Horowicz-Mehler N. CER and the Case for Active Patient Engagement. Patient's Week. Posted September19th, 2011.

Doyle J, Horowicz-Mehler N. How the Biopharmaceutical Industry Can Navigate a Healthcare Ecosystem Increasingly Driven by Demands for Comparative Effectiveness Research. Accepted for Publication in Pharmaceutical Medicine.

Hendlish S, Horowicz-Mehler N, Brixner D, Stern L, Doyle J, Chang J, Hagan M. Contraceptive and Noncontraceptive benefits of the LNG-IUS in a vertically integrated HM). Contraception 2008:78: 36–41

Isaacman DJ, Strutton DR, Kalpas EA, Mehler N, Stern LS, Casciano R, Ciuryla V. The Impact of Indirect (Herd)Protection on the Cost-Effectiveness of Pneumococcal Conjugate Vaccine (PCV7; Prevnar). Review article. Clinical Therapeutics 2008:30(2): 341-357.

Evans CJ, Horowicz-Mehler N. Pharmacoeconomics in Pain Research. In: Wittink, H., Carr, D., eds. Pain Management: Evidence, Outcomes and Quality of Life. A Sourcebook. Oxford, UK. Elsevier Health Sciences, 2008.

Evans C, Schein J, Nelson W, Crespi S, Gargiulo K, Horowicz-Mehler N, Panchal S. Improving Patient and Nurse Outcomes: A Comparison of Nurse Tasks and Time Associated with Two Patient-Controlled Analgesia Modalities Using Delphi Panels. Pain Manag Nurs 2007;8 (2):86-95.

Phillips A, Jacobson J, Magai C, Consedine N, Horowicz-Mehler N, Neugut A. Cancer Incidence and Mortality in the Caribbean. Cancer Invest. 2007;25 (6):476-83.

McNicol E. Horowicz-Mehler N. Fisk RA. Bennett K. Gialeli-Goudas M. Chew PW. Lau J. Carr D. American Pain Society. Management of opioid side effects in cancer-related and chronic noncancer pain: a systematic review. Journal of Pain 2003;4(5):231-256.

Horowicz-Mehler N, McNicol E, Fisk RA et al. Management of opioid-related side effects in cancer-related and chronic noncancer pain: a systematic review. Internal report for the American Pain Society used to support recommendations in the Cancer Pain Guideline.

Poster and Podium Presentations

I. Kurashige, A.Baek, A. Pichardo, S. Myrick, N. Horowicz-Mehler, M. Curran, J. Savola, K. Gabriel, F. Tavakkoli. Enzyme replacement therapy treatment patterns and patient outcomes in late-onset Pompe disease. 17th Annual World symposium (February 8-11, 2021, online).

IQVIA, Bristol-Myers Squibb. Scrip Award Finalist, Best use of Real-World Evidence (RWE), Project: I-O Optimise.2018. 14th Annual Scrip Award Ceremony, London (November 28, 2018).

AS. Chawla, N. Horowicz-Mehler, EC. Faulkner, S. Strassels, L. Saake. Clinical Practice of Intrathecal Drugs for Management of Pain and Spasticity: A Multinational Cross-Sectional Survey of Healthcare Providers. Poster presented at the 19th Annual International ISPOR Meeting (May 31-June 4, 2014, Montreal, Canada).

N. Horowicz-Mehler, C. Tao, JJ. Doyle, E. Faulkner. An Analyses of Real-World Data Trends in Global HTA Markets. Poster presented at the 19th Annual International ISPOR Meeting (May 31-June 4, 2014, Montreal, Canada).

S. Kotak, J. Mardekian, N. Horowicz-Mehler, A. Shah, A. Burgess, J. Kim, E. Gemmen, H. Boyd, A. Koenig. Impact of Etanercept Therapy on Disease Activity and Health-related Quality of Life in Moderate Rheumatoid Arthritis Patients: Population from a National British Observational Cohort. Poster to be presented at the Annual European Congress of Rheumatology (EULAR) (June 12-15, 2013, Madrid, Spain).

Crawley JA, Horowicz-Mehler N, Hawryluk E, King F. Impact of Opioid-Induced Constipation: a Multinational Cross-Sectional Survey of Patients and Health Care Providers. Poster presented at the 18th Annual International ISPOR Meeting (May18-22, 2013, New Orleans LA, USA).

Teal S, Gaine S, Horowicz-Mehler N, Gemmen E, Kim J, Burgess A, Mardekian J, Hoeper M.M. Patterns Of Use Of Sildenafil For Pulmonary Arterial Hypertension: A Real-World Assessment From Germany And Ireland. Poster presented at the 2013 American Thoracic Society Annual Meeting (May 17-22, 2013, Philadelphia PA, USA).

Sidovar M, Horowicz-Mehler N, Hawryluk E, Cascade E, McCarthy S. Patient-Reported Burden of Walking Impairment in Multiple Sclerosis. Poster presented at the 17th Annual International ISPOR Meeting (June 2-6, 2012, Washington DC, USA).

McCoy M, Horowicz-Mehler N, Law A. The impact of possible undiagnosed heavy menstrual bleeding (HMB) on presenteeism and activities outside of work. Poster presented at the 2011 ACCP Annual Meeting (October 15-17, 2011, Pittsburgh, USA).

Horowicz-Mehler N, Nixon M, Casazza C, Gemmen E, Doyle J, Cascade E. Patient-Centric Observational Study on Correlates of Intent to Persist with Treatment: A Regression Model in Osteoporosis. Poster presented at the 16thAnnual International ISPOR Meeting (May 21-25, 2011, Baltimore, USA).

Hawriluk E, Horowicz-Mehler N, Popli M. Drug Prescribing Behavior for the Treatment of Heavy Menstrual Bleeding. Poster presented at the 16th Annual International ISPOR Meeting (May 21-25, 2011, Baltimore, USA).

Horowicz-Mehler N, Doyle J, Arikian S, Hagan M. A Comparative Effectiveness Index to Inform Clinical Decisions. Accepted for podium presentation: Evolving Concepts in Outcomes Research at the 16th Annual International ISPOR Meeting (May 21-25, 2011, Baltimore, USA).

Horowicz-Mehler N, Doyle J. The Benefits and Risks of using Observational Research to Measure CER. Accepted for poster presentation at the 2010 Academy Health's Annual Research Meeting (June 27-29,

Boston, USA).

Horowicz-Mehler N, Sepulveda B, White C, Doyle J. The Impact of the FDA's Risk Evaluation and Mitigation Strategies (REMs) Initiative on Prescription Pattern for Drugs Approved Under the REMs Program and Relevant non-REMs Competitors. Accepted for poster presentation at the 15th Annual International ISPOR Meeting (May 15-19, 2010, Atlanta, USA).

Horowicz-Mehler N, Sepulveda B, Doyle J. Medicare Part D's Impact on Utilization, Average Retail Price, and Out-of-Pocket Costs for Oral Chemotherapeutics and a Comparative Market Basket of Drugs. Accepted for poster presentation at the 11th Annual International ISPOR Meeting (November 8-11, 2008, Athens, Greece).

Sepulveda B, Horowicz-Mehler N, Doyle J. The Effects of NICE HTAs on Prescription Volume, Average Retail Price and Average Out-Of-Pocket Costs of Drugs Deemed Medically Necessary for Medicare Part D Reimbursement in the US. Accepted for poster presentation at the 11th Annual International ISPOR Meeting (November 8-11, 2008, Athens, Greece).

Brixner DI, Horowicz-Mehler N, Stern L, Doyle J, Dolgitser M, Hagan M. Contraceptive And Non-Contraceptive Benefits Of A Levonorgestrel-Releasing Intrauterine System In A Vertically Integrated HMO. Accepted for poster presentation at the 12th Annual International ISPOR Meeting (May 19-23, 2007, Arlington, VA).

Saadi RH, Horowicz-Mehler N, Crawford B, Espindle D, Marquis P, Mody V. Developing and Validating the International Spinal Cord Injury Scale (ISCIS). Accepted for poster presentation at the Third World Congress of the ISPRM Meeting (April 10-15, 2005, São Paulo, Brazil).

Saadi RH, Horowicz-Mehler N, Crawford B, Espindle D, Marquis P, Mody V. The Development and Validation of the International Spinal Cord Injury Scale (ISCIS). Accepted for oral presentation at the 31st Annual Scientific ASIA Meeting (May 12-14, 2005, Dallas, Texas). (Manuscript to be submitted to Journal of Spinal Cord Medicine)

Crawford B, Baron F, Evans C, Horowicz-Mehler N. Economic And Outcomes Research In The Real World: Evaluation Of Its Relevance. Presented at the 8th Annual International ISPOR Meeting (May 18-21, 2003, Arlington, VA). Value in Health 2003;6(3):301.

Horowicz-Mehler N, Evans C, Crawford B, Mertzanis P, Pena B, Wong J, Mayne TJ. Structural Equation Modeling in a Trial of Rheumatoid Arthritis Patients: Indicators of Satisfaction with Pain Medication and Intention to comply with Treatment. Presented at the Annual European Congress of Rheumatology "EULAR 2002" (June 12-15, 2002, Stockholm, Sweden).

Schumann R, Angelis M, Zabala L, Horowicz N, Goudas LC, Carr DB. Optimal Pain Management for Adult-to-Adult Living Liver Donation: Epidural Blockade and Field Infiltration. Presented at the International Liver Transplantation Society 7th Annual Congress (July 11-14, 2001, Berlin, Germany). Liver Transplantation 2001;7(6):278.

Webinars and Speaking Engagements / Moderation

Nathalie Horowicz-Mehler, PhD. How RWD and AI can support cancer research and public health initiatives such as health equity Women's Health Tech Wednesdays | HITLAB Virtual Stage Webinar (May 25,2022) https://lnkd.in/gcDCBdSj https://www.youtube.com/watch?v=pS0L_jkM5CY

Nathalie Horowicz-Mehler, Chirag Ghai, Roberto Uhera. Unlock and Accelerate the Value of Your Organization's RWE Capabilities: Actionable Ways to Achieve Success Through Education and Training. Webinar (July 22, 2021)

Nathalie Horowicz-Mehler, Tony Gottschalk, and Madhav Namjoshi. Is Your Real-World Data Credible?

Tips to identify and evaluate the right RWD for your organization (July 28, 2020).

Nathalie Horowicz-Mehler, and James Anderson. Evidence strategies and evidence platforms. IQVIA Webinar (September 27, 2017)

Nancy Dreyer, and Nathalie Horowicz-Mehler. Use of RWE in Clinical Development to Enhance Regulatory Submissions. Complementary innovative trial designs can enrich randomized control trial data. (April 7, 2020)

Nathalie Horowicz-Mehler. Exploring New Opportunities in Real-World Insights. QuintilesIMS Research Forum Webinar (May, 26, 2017) link to RWE in Clinical Development

Jon Resnick, John Doyle, Nathalie Horowicz-Mehler, Dan Simpson, and James Anderson. BMS – Using real-world evidence to shape the immuno-oncology landscape. IQVIA Newsletter (February 23, 2017).

Panelist for Next Generation Registries Workshop, a thought leadership initiative organized by the Registry Practice Center of Excellence and the IQVIA Institute for Human Data Science, in collaboration with the Center for Advanced Evidence Generation and the RWTS Integrated Health Practice. Virtual (July 13, 2021)

Panelist at alumni panel "Careers for Doctoral Graduates" for Columbia University's Mailman School of Public Health students, incoming students, and alumni. Virtual (July 8, 2021)

Moderator for Merck's MRL Center for Observational and Real-World Evidence (CORE) Global Pharma Scientific Input Engagement (SIE). Virtual (June 7-9, 2021)

Moderator for Merck's MRL Center for Observational and Real-World Evidence (CORE) Global Pharma Scientific Input Engagement (SIE). New Orleans (May 22&23, 2019)

Moderator for Merck's MRL Center for Observational and Real-World Evidence (CORE) Scientific Input Engagement (SIE). Philadelphia (April 1, 2019)

Nathalie Horowicz-Mehler. Evidence Platforms or Investing in Value Creation. IMPACCT RWE Conference, Boston (September 26, 2018). https://impacct-rwe.com/

Nathalie Horowicz-Mehler. Evidence Generation Programs & Platforms. TORCH IX IQVIA Conference, Philadelphia (May 16, 2018)

Financial Times US Healthcare and Life Sciences Summit, New York (May 18, 2017). Panel discussion around "How will the future of healthcare in the US unfold" https://live.ft.com/Events/2017/FT-US-Healthcare-Life-Sciences-Summit-2017

Center for Healthcare Innovation (CHI), New York (October 12, 2017). Healthcare executives roundtable around "Healthcare Value in a Consumer-Oriented, Patient-Centric Era" https://www.chisite.org/wp-content/uploads/Roundtable_2017.pdf

Blogs and Podcasts

Jeff Elton, PhD; Elizabeth Sweeney, PhD; Nathalie Horowicz-Mehler, PhD, and Catherine Richards, PhD. While we are all COVID-Fatigued, the Effects of the Early Pandemic Are Real – An Imperative to Act on Behalf of Cancer Patients. Aug 2, 2022. https://www.concertai.com/blog/2022/08/an-imperative-to-act-on-behalf-of-cancer-patients/

Jeff Elton, PhD and MPH; Nathalie Horowicz-Mehler, PhD and MPH. As I shared in this conversation with Jeff Elton here at ConcertAI, Real-world Evidence is arriving at a point "that is so critical and complementary to clinical trials, with standards comes higher quality, confidence and higher use" bringing

to the fore under-represented population and its associated public health impact. https://www.linkedin.com/in/nathalie-horowicz-mehler-phd-9516823/recent-activity/shares/

Jeff Elton, PhD; Catherine Richards, PhD, MPH; Nathalie Horowicz-Mehler, PhD, MPH. Perspective on the foundational role of research-grade RWD in providing cancer-specific and pan-tumor views of the current standard of care and its place in the total R&D system. May 31,2022. https://www.concertai.com/blog/2022/05/why-rwd-is-foundational-to-biopharma-clinical-development/

 $ttp://www.quintiles.com/blog/how-to-get-payers-on-your-side \cdot \ http://www.quintiles.com/blog/companion-devices-will-become-mainstay-but-how-will-they-be-paid-for$

http://www.quintiles.com/blog/sharing-risk-with-payersN Horowicz-Mehler. Why join the Enterprise Solutions team at IQVIA?

https://www.youtube.com/watch?v=26mpyWj mkc&feature=share&app=desktop

21 Resolutions for advancing human health in 2021 https://www.iqvia.com/en/locations/united-states/blogs/2021/01/21-resolutions-for-advancing-human-health-in-2021?utm_campaign=2021_USBlogResolutions_USCAusa_AS&utm_source=linkedin&utm_medium=social&utm_content=social-linkedin_us-blog-resolutions&sf136147394=1

Part 1: Using RWE in Clinical Development to Enhance Regulatory Submissions – The growing acceptance of regulators globally

Part 2: Using RWE in Clinical Development to Enhance Regulatory Submissions – How can RWE strengthen a regulatory package?

Is Your Real-World Data Credible? 2-part series

- · Part 1: https://www.iqvia.com/locations/united-states/blogs/2021/03/is-your-real-world-data-credible-part-1
- · Part 2: https://www.iqvia.com/locations/united-states/blogs/2021/03/is-your-real-world-data-credible-part-2

Project Experience

Established a peer-to-peer scientific advisory force to potentiate innovation in RWE leveraging RWD, technology, and AI to support regulators and other stakeholders' decision making in a dynamic multimodal oncology market.

Translated evidentiary needs into fit-for-purpose custom RW datasets and RWE studies ranging from RW control arms to dynamic registries assessing long-term outcomes, to support regulatory or HTA submissions.

Worked alongside Life Sciences clients to generate and deliver innovative RW solutions by leveraging the full spectrum of data & analytics, technology and scientific expertise at a large CRO.

Established an innovation lifecycle for novel offerings from ideation, proof of concept, standardization and growth.

Lead the strategic support for a multi-year collaboration between a large Pharma and IQVIA to build a RWD platform in Europe and Canada generating ongoing, comprehensive RWD to inform clinical & reimbursement decisions and improve Public Health outcomes for patients with a thoracic malignancy.

Led an initiative to enhance the clinical development pipeline and associated regulatory success for a large Pharmaceutical via innovative hybrid RCT-RWE designs such as pragmatic studies, external control arms and innovative extension studies leveraging fit-for-purpose RWD.

US lead for a searchable web platform centralizing information on global monitoring of HTA Agency across therapeutic areas in key markets to identify clinical, economic and humanistic endpoints associated with positive review.

Developed and conducted psychometric validation of patient reported outcomes (PROs) to support regulatory claims including 1) a measure of symptomatic malignant ascites impact in late stage cancer; 2) a responder index in chronic low back pain indicating patient-perceived clinically meaningful improvement while minimizing placebo response rates in clinical trials; 3) identifying the best definition for inclusion of an "osteoarthritis flare" as a clinical outcome and analysis of the outcome's responsiveness.

Lead health economics projects including 1) cost-effectiveness model for a spinal cord injury treatment to establish pricing thresholds and strategy for market launch; 2) a model comparing overall costs between cryoprecipitate and factor concentrate for the treatment of hemophilia.