MARIANNE CUNNINGTON, PH.D.
Managing Principal

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Dr. Cunnington specializes in regulatory epidemiology, including the design and execution of real-world post-marketing safety and effectiveness studies, as well as real-world studies to support the approval of new products through innovative regulatory pathways. Her research expertise includes design, negotiation, and execution of real-world components of risk management plans for new product submissions with regulators across multiple geographies (US, UK, Europe, Japan, South Korea); post-approval safety studies in the EU; post-marketing requirement and commitment studies in the US; and pregnancy registries. Prior to joining Analysis Group, Dr. Cunnington spent more than 20 years as a pharmaceutical industry epidemiologist focusing on the generation of real-world evidence (RWE) to support the development and life cycle management of vaccines and pharmacological therapies. Dr. Cunnington held several senior epidemiology positions within Novartis and GlaxoSmithKline (GSK). At GSK, she chaired the peer review forum for all pharmaceutical RWE projects, provided epidemiological expertise for the company's Global Safety Board, and was a managing board member of the Innovative Medicines Initiative's public-private partnership, building an integrated European real-world data network to monitor medication safety in pregnancy. Dr. Cunnington serves on the board of the International Society for Pharmacoepidemiology as an elected representative of European industry and service providers.

EDUCATION

2003	Ph.D., infectious disease epidemiology, London School of Hygiene & Tropical Medicine, UK
1998	M.Phil., epidemiology, University of Cambridge, UK
1997	B.A., biological sciences, University of Oxford, UK

PROFESSIONAL EXPERIENCE

2022–Present	Analysis Group, Inc. *Managing Principal (2026–Present)* *Vice President (2022–2026)*
2015–2022	GSK *Research and Safety Science Head, Epidemiology, (2019–2022)* *Interim Head, Epidemiology, (2018–2019)* *Senior Director and (Group) Therapy Area Lead, Real World Evidence and Epidemiology (2015–2019)*

2011–2015	Novartis Vaccines *Head of Epidemiology (2014–2015)* *Senior Epidemiologist (2011–2014)*
2010–2011	Medical Research Council, The Gambia *Epidemiologist, Viral Diseases Program – Sabbatical*
2003–2010	GSK *Associate Director, Epidemiology (2007–2010)* *Manager, Epidemiology (2005–2007)* *Principal Epidemiologist, Epidemiology (2003–2005)*
1998–1999	Public Health Laboratory Service Communicable Disease Surveillance Centre *Research Scientist*

SELECTED ARTICLES AND PUBLICATIONS

Yang X, Obeng-Kusi M, Dettling T, Adeyemi A, **Cunnington M**, Liu Q, Lejeune D, Chen G, Duh MS, Jordan JT. Characteristics, treatment patterns, healthcare resource use, and costs among adult patients diagnosed with neurofibromatosis type 1 and plexiform neurofibromas in the United States. *BMC Neurology.* 2026; 26, 410. doi: 10.1186/s12883-026-04868-8

Yang X, Done N, **Cunnington M**, Gao Y, Dettling T, Pfefferkorn J, Young-Xu L, Duh M, Wolters P. Burden Among Caregivers of Adult Patients with Neurofibromatosis Type 1 and Plexiform Neurofibroma in the United States: A Cross-Sectional Survey Study. *Neurology and Therapy*. 2026; 15(4): 1523-1537. doi: 10.1007/s40120-026-00934-y.

Asomaning K, Duh MS, DerSarkissian M, de Luise C, Nguyen C, Cheng M, Lax A, Guo T, **Cunnington M,** Cremieux P, Young-Xu Y, Korves C, Dalle Lucca J, Post-emergency use authorization active safety surveillance study of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine in the Veterans Affairs health system: Findings from a three-year, comprehensive safety assessment program, *Vaccine: X*, 2026; 29. doi: 10.1016/j.jvacx.2026.100791.

Yang X, Done N, **Cunnington M**, Gao Y, Dettling T, Pfefferkorn J, Young-Xu L, Duh M, Wolters P. Clinical and Humanistic Burden Among Adults with Neurofibromatosis Type 1 and Symptomatic Plexiform Neurofibroma in the United States. *Neurology and Therapy*. 2026; 15(2): 597-616. doi: 10.1007/s40120-025-00855-2.

Tazare J, Gibbons D, Smeeth L, Gillespie I, **Cunnington M**, Logie J, Douglas I, Williamson E. Assessment of a Modified High-Dimensional Propensity Score Approach for UK Electronic Health Record Data: Evaluating Upper Gastrointestinal Safety of NSAIDs and COX-2 Inhibitors. *Pharmacoepidemiology and Drug Safety.* 2026; 35(1) : e70319. doi: 10.1002/pds.70319.

Schultze A, Brown J, Logie J, **Cunnington M,** Requena G, Gillespie I, Evans S, Douglas I, Galwey N. Overcoming Time-Varying Confounding in Self-Controlled Case Series with Active Comparators: Application and Recommendations. *American Journal of Epidemiology.* 2025; 194(1): 220-225. doi: 10.1093/aje/kwae216.

Fazio-Eynullayeva E, **Cunnington M**, Mystkowski P, Lv L, Aly A, Yee C, Desai R, Liu C, Duh M, Mattke S. Real-world healthcare resource utilization of Alzheimer's disease in the early and advanced stages: a retrospective cohort study. *Journal of Medical Economics*. 2025; 28(1): 81-88. doi:

10.1080/13696998.2024.2442240.

Baptiste P, Wong A, Schultze A, Clase C, Leyrat C, Williamson E, Teoh M, Mann J, **Cunnington M,** Teo K, Bagdiwala S, Gao P, Tomlinson L, Wing K. Cardiorenal effects of Angiotensin-converting enzyme inhibitors and Angiotensin receptor blockers in people underrepresented in trials: analysis of routinely collected data with validation against a target trial. *American Journal of Epidemiology.* 2024; 193(12): 1785-1795. doi: 10.1093/aje/kwae137.

Baptiste P, Wong A, Schultze A, Clase C, Leyrat C, Williamson E, Powell E, Mann J, **Cunnington M,** Teo K, Bangdiwala S, Gao P, Wing K, Tomlinson L. Effectiveness and risk of ARB and ACEi among different ethnic groups in England: A reference trial (ONTARGET) emulation analysis using UK Clinical Practice Research Datalink Aurum-linked data. *PLOS Medicine.* 2024; 21(9): e1004465. doi: 10.1371/journal.pmed.1004465.

Andresen K, Hinojosa-Campos M, Podmore B, Drysdale M, Qizilbash N, **Cunnington M.** Validity of Routine Health Data To Identify Safety Outcomes of Interest For Covid-19 Vaccines and Therapeutics in the Context of the Emerging Pandemic: A Comprehensive Literature Review. *Drug, Healthcare and Patient Safety.* 2024; 16: 1-17. doi: 10.2147/DHPS.S415292.

Hollestelle MJ, van der Graaf R, Sturkenboom MCJM, **Cunnington M**, van Delden JJM. Building a Sustainable Learning Health Care System for Pregnant and Lactating People: Interview Study Among Data Access Providers. *JMIR Pediatrics and Parenting*. 2024 Feb 8; 7: e47092. doi: 10.2196/47092.Tazare J, Gibbons D, Bokern M, Williamson E, Gillespie I, **Cunnington M,** Logie J, Douglas I. Prevalent new user designs: A literature review of current implementation practice. *Pharmacoepidemiology and Drug Safety.* 2023; 32(11): 1252-1260. doi: 10.1002/pds.5656

Hammill BG, Leimberger JD, Lampron Z, Raman SR, O'Brien EC, Wurst KE, Mountcastle S, **Cunnington M**, Janmohamed S, Curtis LH. Fitness of real-world data for clinical trial data collection: Results and lessons from a HARMONY Outcomes ancillary study. *Clinical Trials.* 2022; doi: 10.1177/17407745221114298

Davitte JM, Stott-Miller M, Ehm MG, **Cunnington MC**, Reynolds RF. Integration of real world data and genetics to support target identification and validation. *Clinical Pharmacology & Therapeutics*. 2022; 111(1): 63-76. doi: 10.1002/cpt.2477.

Baptiste P, Wong A, Schultze A, **Cunnington M**, Dyal L, Mann J, Clase C, Leyrat C, Tomlinson L, Wing K. Real world effects of ACE inhibitors and angiotensin receptor blockers: protocol for an emulation study of the ON-TARGET trial using electronic health records. *BMJ Open*. 2022; 12(3): e051907. doi: 10.1136/bmjopen-2021-051907

Pajouheshnia R, Thurin N, Roberto G, Dodd C, Hyeraci G, Bartolini C, **Cunnington M**, Swertz M, Sturkenboom M, Gini R, et al. From inception to ConcePTION: Genesis of a Network to Support Better Monitoring and Communication of Medication Safety During Pregnancy and Breastfeeding. *Clinical Pharmacology & Therapeutics*. 2022 Jan; 111(1): 321-331. doi: 10.1002/cpt.2476.

Lulic Z, Son H, Yoo SB, **Cunnington M**, Kapse P, Miller D, et al. Free combination of dutasteride plus tamsulosin for the treatment of benign prostatic hyperplasia in South Korea: analysis of drug utilisation and adverse events using the National Health Insurance Review and Assessment Service database. *BMC Urology*. 2021; 21(1): 178. doi: 10.1186/s12894-021-00941-1.

Wurst KE, Sumner KM, Stanislaus D, Powell M, **Cunnington M**. A model for human and animal data integration: Weight of evidence strategy. *Birth Defects Research*. 2020; 112: 1505-1512. doi: 10.1002/bdr2.1775.

Ji W, Liu H, Madhi SA, **Cunnington M**, Zhang Z, Dangor Z, et al. Clinical and Molecular Epidemiology of Invasive Group B Streptococcus Disease among Infants, China. *Emerging Infectious Diseases*. 2019 Nov; 25(11): 2021-2030. doi: 10.3201/eid2511.181647.

Tseng HF, Sy LS, Ackerson BK, Hechter RC, Tartof SY, Haag M, Slezak JM, Luo Y, Fischetti CA, Takhar HS, Miao Y, **Cunnington M**, Solano Z, Jacobsen SJ. Post licensure safety study of a quadrivalent meningococcal conjugate vaccine on adolescents and young adults. *Pediatrics*. 2017 Jan; 139(1): pii: e20162084. doi: 10.1542/peds.2016-2084.

Kwatra G, **Cunnington MC**, Merrall E, Adrian PV, Ip M, Klugman KP, Tam WH, Madhi SA. Prevalence of maternal colonization with Group B *Streptococcus*: systematic review and meta-analysis. *The Lancet Infectious Diseases*. 2016; 16(9): 1076-1084. doi: 10.1016/S1473-3099(16)30055-X.

Rivera L, Sáez-Llorens X, Feris-Iglesias J, Ip M, Saha S, Adrian PV, Madhi SA, Boudville IC, **Cunnington MC**, Casellas JM, Slobod KS. Incidence and serotype distribution of invasive group B streptococcal disease in young infants: a multi-country observational study. *BMC Pediatrics*. 2015; 15(1): 143. doi: 10.1186/s12887-015-0460-2.

Cutland CL, **Cunnington M**, Olugbosi M, Jones SA, Hugo A, Maharaj K, Slobod K, Madhi SA. Lessons learnt from enrolment and follow up of pregnant women and their infants in clinical trials in South Africa, a low-middle income country. *Vaccine*. 2015; 33(47): 6406-12. doi: 10.1016/j.vaccine.2015.08.040.

Liu HY, Zeng HL, Wang WD, Deng QL, Margarit Y Ros I, Rinaudo CD, Swarthout T, **Cunnington M**, Ji WJ, Geng GZ. Burden of Invasive Group B Streptococcal (GBS) Disease in Young Infants in China-An Observational Study. *International Journal of Clinical and Experimental Medicine*. 2015; 8: 13699-13707.

Villanueva-Uy ME, Wongsiridej P, Santawesin V, Chiu V, Tallo V, Nazaire-Bermal N, Bock H, **Cunnington M**, Nan C, Boudville I. The burden of invasive neonatal Group B Streptococcus (GBS) disease in Thailand and the Philippines. *The Southeast Asian Journal of Tropical Medicine and Public Health*. 2015; 46: 728-37.

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Cunnington MC, Weil JG, Messenheimer JA, Ferber S, Yerby M, Tennis P. Final results from 18 years of the International Lamotrigine Pregnancy Registry. *Neurology*. 2011; 76: 1817-23.

Cunnington MC, Webb DJ, Irizarry MC, Manjunath R. Risk factors for antiepileptic drug regimen change in patients with newly diagnosed epilepsy. *Epilepsy & Behavior*. 2011; 21: 168-72.

Charlton RA, Weil JG, **Cunnington MC**, Ray S, de Vries CS. Comparing the General Research Practice Database and the UK Epilepsy and Pregnancy Register as tools for postmarketing teratogen surveillance: anticonvulsants and the risk of major congenital malformations. *Drug Safety*. 2011; 34: 157-71.

Charlton RA, Weil JG, **Cunnington MC**, de Vries CS. Identifying major congenital malformations in the General Research Practice Database (GPRD): A study reporting on the sensitivity and added value of photocopied medical records and free text in the GPRD. *Drug Safety*. 2010; 33: 741-50.

Cunnington MC, Ephross SA, Churchill P. The safety of sumatriptan during pregnancy: what have we learned? *Headache*. 2009; 49: 1414-1422.

Charlton R, **Cunnington M**, Weil J, de Vries C. Regarding the need, or lack thereof, of a comparator group for pregnancy registries. *Birth Defects Research Part A: Clinical and Molecular Teratology*. 2009; 85: 808.

Faught E, Weiner JR, Guerin A, **Cunnington MC**, Duh MS. Impact of non-adherence to antiepileptic drugs on healthcare utilisation and costs: Findings from the RANSOM study. *Epilepsia*. 2009; 50: 501-9.

Cunnington M, Messenheimer J. Pregnancy registries: strengths, weaknesses and bias in the interpretation of pregnancy registry data. *International Review of Neurobiology*. 2008; 83: 283-304.

Faught E, Duh MS, Weiner JR, Guerin A, **Cunnington MC**. Non adherence to anti-epileptic drugs and increased mortality: findings from the RANSOM study. *Neurology*. 2008; 71(20): 1572-8.

Cunnington MC, Qizilbash NQ, Webb DJ, Blum D, Funk M, Weil JG. Risk of ischaemic cardiovascular events from selective cyclo-oxygenase-2 inhibitors in osteoarthritis. *Pharmacoepidemiology and Drug Safety*. 2008; 17(6): 601-08

Charlton RA, **Cunnington MC**, De Vries CS, Weil JG. Data resources for investigating drug exposure during pregnancy and associated outcomes. *Drug Safety*. 2008; 31(1): 39-51.

Cunnington MC, Ferber S, Quartey G, International Lamotrigine Pregnancy Registry Scientific Advisory Committee. Effect of dose on the frequency of major birth defects following fetal exposure to lamotrigine monotherapy in an international observational study. *Epilepsia*. 2007; 48(6): 1207-10.

Hawkes CH, Giovannoni G, Kier G, **Cunnington MC**, Thompson E.J. Seroprevalence of herpes simplex virus type two in multiple sclerosis. *Acta Neurologica Scandinavica*. 2006; 114(6): 363-7.

Cunnington MC, Tennis P, and The International Lamotrigine Pregnancy Registry Scientific Advisory Committee. Pregnancy Outcomes over 11 years of monitoring in the International Lamotrigine Pregnancy Registry. *Neurology*. 2005; 64: 955-60.

Cunnington MC. The International Lamotrigine Pregnancy Registry Update for the Epilepsy Foundation. *Epilepsia*. 2004; 45(11): 1468.

Morris-Cunnington MC, Edmunds WJ, Brown DWG, Miller E. Immunity and exposure to hepatitis A virus in a pre-adolescent children from a multi-ethnic inner city area. *Communicable Disease and Public Health*. 2004; 7(2): 134-7.

Morris-Cunnington MC, Brown DWG, Pimenta JM, Robinson NJ, Miller E. New estimates of HSV-2 seroprevalence in England: "high" but stable seroprevalence over the last decade. *Sexually Transmitted Diseases*. 2004; 31(4): 243-6.

Morris-Cunnington MC, Edmunds WJ, Brown DWG, Miller E. A population-based seroprevalence study of hepatitis A virus in England and Wales using oral fluid. *American Journal of Epidemiology*. 2004; 159(8): 786-94.

Morris-Cunnington MC, Edmunds WJ, Miller E, Brown DWG. A novel method of oral fluid collection to monitor immunity to common viral infections. *Epidemiology & Infection*. 2004; 132: 32-42.

Morris MC, Cohen BJ, Andrews NJ, Brown DWG. Stability of total and rubella specific IgG in oral fluid samples. The effect of time and temperature. *Journal of Immunological Methods*. 2002; 266(1-2): 111-116.

Morris MC, Edmunds WJ. The changing epidemiology of infectious mononucleosis. *Journal of Infection*. 2002; 45: 107-109.

Morris MC, Edmunds WJ, Miller E, Brown DWG. Oral fluid collection by post – a pilot of two approaches. *Public Health*. 2002; 116: 113-119.

Morris MC, Edmunds WJ, Hesketh LM, Vyse AJ, Miller E, Morgan-Capner P, Brown DWG. Sero-epidemiological patterns of Epstein-Barr and herpes simplex viruses (HSV-1 and HSV-2) in England and Wales. *Journal of Medical Virology*. 2002; 67(4): 522-7.

Morris MC, Gay NJ, Hesketh LM, Morgan-Capner P, Miller E. The changing epidemiological pattern of hepatitis A in England and Wales. *Epidemiology and Infection*. 2002; 128: 457-463.

Morris MC, Rogers PA, Kinghorn G. Is bacterial vaginosis a sexually transmitted infection? *Sexually Transmitted Infections*. 2001; 77(1): 63-68.

Morris MC, Nicoll A, Simms I, Wilson J, Catchpole M. Bacterial vaginosis: a public health review. *British Journal of Obstetrics and Gynaecology*. 2001; 108: 439-450.

Book Chapters

Covington DL, Doi PA, **Cunnington MC**, Kennedy DL, Tilson HH. "Pregnancy Registries," in Hartzema, Tilson and Chan, *Pharmacoepidemiology and Therapeutic Risk Management*. Harvey Whitman, 2008.

Cunnington M, Messenheimer J. "Pregnancy registries: strengths, weaknesses and bias. Interpretation of pregnancy registry data," in *Epilepsy in Women: The Scientific Basis for Clinical Management*, edited by Gidal BE and Harden CL. *International Review of Neurobiology*. 2008; vol. 83.

Reports

A review of measles case fatality rates and the principles of measles control and elimination, for the World Health Organization. 2002.

Measles case fatality rates and the principles of measles control and elimination, for the World Health Organization. 2000.

PRESENTATIONS AND SPEAKING ENGAGEMENTS

40+ poster and oral presentations at international conferences

TEACHING APPOINTMENTS

2016–Present	London School of Hygiene & Tropical Medicine, Certificate in Pharmacoepidemiology and Pharmacovigilance
2012–Present	University of Siena, Master's in Vaccinology

SELECTED HONORS AND AWARDS

2022	Data Science Innovation Challenge, PHUSE FDA
2018 and 2020	Innovation Performance Trust Award, GSK

PROFESSIONAL ASSOCIATIONS AND MEMBERSHIPS

2015–Present	ISPE *Member*
2023–Present	*Board member* representing industry and service providers in Europe

JOURNAL PEER REVIEWER

Drug Safety

Pharmacoepidemiology and Drug Safety

Nature Communications

LANGUAGES

French (fluent)