

**MARIANNE CUNNINGTON, PH.D.**  
**Vice President**

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Dr. Cunnington has over 20 years of experience as a pharmaceutical industry epidemiologist. She specializes in the generation of real-world evidence (RWE) in support of the development and life cycle management of pharmaceutical and vaccine products, with a particular focus on regulatory risk management strategies and product benefit-risk assessments. Dr. Cunnington's research expertise includes the design, negotiation, and execution of real-world components of risk management plans for new product submission to regulators in the US, UK, EU, Japan, and South Korea, including studies of post-approval safety in the EU; post-marketing requirements and commitments in the US; and pregnancy registries. Prior to joining Analysis Group, she served in several senior epidemiology positions at pharmaceutical companies, including as the chair of GSK's peer review forum for all pharmaceutical RWE projects; as a member of GSK's Global Safety Board; as head of epidemiology at Novartis Vaccines; and as a managing board member of Innovative Medicines' public-private partnership initiative to build an integrated European real-world data (RWD) network to monitor medication safety in pregnancy.

**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.  
*Vice President*

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*

### TEACHING APPOINTMENTS

- 2016–Present Certificate in Pharmacoepidemiology and Pharmacovigilance, London School of Hygiene & Tropical Medicine, UK
- 2011–Present Master in Vaccinology, University of Siena, Italy

### ARTICLES AND PUBLICATIONS

- 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. From inception to ConcePTION. *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. <http://dx.doi.org/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 metaanalysis. *The Lancet Infectious Diseases*. 2016; 16(9): 1076-1084. doi: 10.1016/S1473-3099(16)30055-X. Epub 2016 May 25.

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; S0264-410X(15)01167-6. 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.

Nan C, Dangor Z, Edwards M, Cutland C, Madhi S, **Cunnington M**. Maternal Group B Streptococcus colonization and stillbirth – a systematic review. *British Journal of Obstetrics and Gynaecology*. 2015; 122(11): 1437-45.

Sinclair S, **Cunnington M**, Messenheimer J, Weil J, Cragan J, Lowensohn R, Yerby M, Tennis P. Advantages and problems with pregnancy registries: observations and surprises throughout the life of the International Lamotrigine Pregnancy Registry. *Pharmacoeconomics and Drug Safety*. 2014; 23(8): 779-86.

**Cunnington M**, Kortsalioudaki C, Heath P. Genitourinary pathogens and preterm birth. *Current Opinion in Infectious Diseases*. 2013; 26: 219-230.

Dagnew AF, **Cunnington MC**, Dube Q, Edwards MS, French N, Heyderman RS, Madhi SA, Slobod K, Costa Clemens SA. Variation in reported neonatal group B streptococcal disease incidence in developing countries. *Clinical Infectious Diseases*. 2012; 55: 91-102

**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**, Quizilbash 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 M.C.,** Edmunds, W.J., Hesketh, L.M., Vyse, A.J., Miller E, Morgan-Capner, P., Brown, D.W.G. 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**

More than 40 poster and oral presentations at international conferences

### **SELECTED HONORS AND AWARDS**

2022            Data Science Innovation Challenge, PHUSE/FDA

2018, 2020    Innovation Performance Trust Award, GSK

### **PROFESSIONAL ASSOCIATIONS AND MEMBERSHIPS**

2015–Present   International Society for Pharmacoepidemiology (ISPE)  
*Member*

### **LANGUAGES**

French (fluent)