



## Curriculum Vitae

### Personal information Torbjörn Callréus

#### Work experience

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April 1989-April 1994 Physician Swedish National Health Service (Sweden)

- Short-term assignments in Clinical Pharmacology, General Practice and Internal Medicine. Internship at Malmö University Hospital.

April 1994-April 2000 Physician Department of Clinical Pharmacology, Lund University Hospital (Sweden)

May 2000-September 2003 Global Drug Safety Physician AstraZeneca, Lund (Sweden)

December 2003-August 2006 Research Fellow in Pharmacoepidemiology University of Southern Denmark, Odense (Denmark)

August 2004-August 2006 External Medical Advisor Danish Medicines Agency, Pharmacovigilance Unit, Copenhagen (Denmark)

September 2006-September 2007 Director Clinical Safety Merck Serono, Geneva (Switzerland)

October 2007-January 2009 Senior Medical Advisor Division of Vaccine, Statens Serum Institut, Copenhagen (Denmark)

February 2009-September 2017 Chief Medical Officer Danish Medicines Agency, Clinical Trials and Pharmacovigilance Units, Copenhagen (Denmark)

- Co-opted Expert, Pharmacovigilance Working Party at the European Medicines Agency (March 2010-June 2012)
- National Expert on Secondment, European Medicines Agency, Risk Management Section, London, United Kingdom (March 2012-January 2013)
- Alternate member, Pharmacovigilance Risk Assessment Committee at the European Medicines Agency (April 2014-September 2017)
- Member, Scientific Advice Working Party at the European Medicines Agency (October 2015-December 2017)

May 2019- Present External Expert Malta Medicines Authority, San Gwann (Malta)

- Member of the Innovation Task Force at the European Medicines Agency (March 2023-Present)

#### Education and training

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August 1979-June 1980 Liberal Arts Studies Homestead High School, Cupertino, CA (United States)

September 1982-December 1982 Studies in French Institut Franco-Scandinave, Aix-en-Provence (France)

January 1983-January 1989 MD Faculty of Medicine at Lund University (Sweden)

January 1989-January 1991 Studies in Economics and Business Administration (57 ECTS) Stockholm University and Sundsvall College (Sweden)

April 1994-May 1999 PhD in Clinical Pharmacology Faculty of Medicine at Lund University (Sweden)

February 2001-July 2001 Certificate in Pharmacoepidemiology and Pharmacovigilance London School of Hygiene and Tropical Medicine (United Kingdom)

May 2008 Advanced Course of Vaccinology Fondation Mérieux, Veyrier-du-Lac (France)

August 2012 Visiting Researcher Fondation Brocher, Hermance (Switzerland)

November 2017-September 2019 Visiting Researcher Pharmacovigilance Research Group, University of Copenhagen (Denmark)

January 2022- Present Visiting Researcher and Guest Lecturer Georgetown University, Washington DC (United States)

- Visiting Researcher, Kennedy Institute of Ethics (January 2022-May 2022)
- Member of the "Emerging Technologies Working Group" (October 2022-Present)
- Guest Lecturer, Department of Microbiology and Immunology, School of Medicine (March 2023-Present)

#### Additional information

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##### Publications

1. Grundemar L, Kahl U, Callreus T, Langel U, Bienert M, Beyermann M. Ligand binding and functional effects of systematic double D-amino acid residue substituted neuropeptide Y analogs on Y1 and Y2 receptor types. *Regul Pept.* 1996 Apr 23;62(2-3):131-6.
2. Callreus T, Hoglund P. Pharmacokinetics and antidiuretic effect of intravenous administration of desmopressin in

- orally overhydrated male volunteers. *Pharmacol Toxicol*. 1998 Dec;83(6):259-62.
3. Callreus T, Lundahl J, Broeders A, Hoglund P. Pharmacokinetics and antidiuretic effect of a new vasopressin analogue (F992) in overhydrated male volunteers. *Eur J Clin Pharmacol*. 1999 Jun;55(4):293-8.
  4. Callreus T, Lundahl J, Hoglund P, Bengtsson P. Changes in gastrointestinal motility influence the absorption of desmopressin. *Eur J Clin Pharmacol*. 1999 Jun;55(4):305-9.
  5. Callreus T, Odeberg J, Lundin S, Hoglund P. Indirect-response modeling of desmopressin at different levels of hydration. *J Pharmacokinet Biopharm*. 1999 Oct;27(5):513-29.
  6. Callreus T. Doctoral dissertation: "Pharmacokinetic and pharmacodynamic analysis of antidiuretic peptides" (ISBN: 91-628-3568-8, May 1999, Faculty of Medicine, Lund University, Sweden).
  7. Callreus T, Holmquist IB, Lundin S, Hoglund P. The influence of lithium on the antidiuretic effect of desmopressin. *J Pharm Pharmacol*. 2002 Sep;54(9):1279-85.
  8. Odeberg JM, Callreus T, Lundin S, Roth EB, Hoglund P. A pharmacokinetic and pharmacodynamic study of desmopressin: evaluating sex differences and the effect of pre-treatment with piroxicam, and further validation of an indirect response model. *J Pharm Pharmacol*. 2004 Nov;56(11):1389-98.
  9. Callreus T. Sentinel systems are needed for long term adverse drug reactions [Letter]. *BMJ*. 2005 Jan 29;330(7485):255-6.
  10. Callreus T, Ekman E, Andersen M. Hyponatremia in elderly patients treated with desmopressin for nocturia: a review of a case series. *Eur J Clin Pharmacol*. 2005 Jun;61(4):281-4.
  11. Callreus T. The precautionary principle and pharmaceutical risk management. *Drug Saf*. 2005;28(6):465-71.
  12. Callreus T. Use of the Dose, Time, Susceptibility (DoTS) Classification Scheme for Adverse Drug Reactions in Pharmacovigilance Planning. *Drug Saf*. 2006;29(7):557-66.
  13. Callreus T, Agerskov-Andersen U, Hallas J, Andersen M. Cardiovascular drugs and the risk of suicide: a nested case-control study. *Eur J Clin Pharmacol*. 2007 Jun;63(6):591-6.
  14. Callreus T. Use of desmopressin in elderly patients in Denmark. *Pharmacoepidemiol Drug Saf*. 2007 Sep;16(9):995-8.
  15. Callreus T. On pharmaceutical risk minimization. *Drug Saf*. 2008;31(9):737-42.
  16. Callreus T, Svanstrom H, Nielsen NM, Poulsen S, Valentiner-Branth P, Hviid A. Human papillomavirus immunisation of adolescent girls and anticipated reporting of immune-mediated adverse events. *Vaccine*. 2009 May 14;27(22):2954-8.
  17. Callreus T. Perceptions of vaccine safety in a global context. *Acta Paediatr*. 2010 Feb;99(2):166-71.
  18. Lyngvig J, Callreus T, Helboe P, Engraff T. Drug development-travelling together? *MedNou* 2010 July/August, vol 4, No7:12.
  19. Svanstrom H, Callreus T, Hviid A. Temporal data mining for adverse events following immunization in nationwide Danish healthcare databases. *Drug Saf*. 2010 Nov 1;33(11):1015-25.
  20. Folkenberg M, Callreus T, Svanstrom H, Valentiner-Branth P, Hviid A. Spontaneous reporting of adverse events following immunisation against pandemic influenza in Denmark November 2009-March 2010. *Vaccine*. 2011 Feb 1;29(6):1180-4.
  21. Pasternak B, Svanstrom H, Callreus T, Melbye M, Hviid A. Use of Angiotensin receptor blockers and the risk of cancer. *Circulation*. 2011 Apr 26;123(16):1729-36.
  22. Callreus T. The New EU Legislation on Pharmacovigilance and Changing Models for Drug Development. *Drug Saf*. 2011 Jun 1;34(6):529-30.
  23. Mt-Isa S, Tzoulaki I, Callreus T, Micaleff A, Ashby D. Weighing risks and benefits of medicines: concepts and approaches. *Drug Discovery Today: Technologies* 8 (2011), pp. 29-35.
  24. Larsen TB, Rasmussen LH, Skjoth F, Due KM, Callreus T, Rosenzweig M, Lip GY. Efficacy and safety of dabigatran etexilate and warfarin in 'real world' patients with atrial fibrillation: a prospective nationwide cohort study. *J Am Coll Cardiol*. 2013 Jun 4;61(22):2264-73.
  25. Callreus T. Pharmacovigilance and Public Health Ethics. *Pharmaceut Med*. 2013;27(3):157-164.
  26. Larsen TB, Rasmussen LH, Skjoth F, Due KM, Callreus T, Rosenzweig M, Lip GY. Reply to Letter to the Editor: Response to Siphai et al. *J Am Coll Cardiol*. 2013 Jun 26.
  27. Callreus T & Schneider C. The Emergence of Regulatory Science in Pharmaceutical Medicine. *Pharmaceut Med*. 2013;27(6):345-351.
  28. Mt-Isa S, Hallgreen CE, Wang N, Callreus T, Genov G, Hirsch I, Hobbiger SF, Hockley KS, Luciani D, Phillips LD, Quartey G, Sarac SB, Stoeckert I, Tzoulaki I, Micaleff A, Ashby D; IMI-PROTECT benefit-risk participants. Balancing benefit and risk of medicines: a systematic review and classification of available methodologies. *Pharmacoepidemiol Drug Saf*. 2014 Jul;23(7):667-78.
  29. Berendt L, Callreus T, Petersen LG, Bach KF, Poulsen HE, Dalhoff K. From protocol to published report: a study of consistency in the reporting of academic drug trials. *Trials*. 2016 Feb 19;17(1):100.
  30. Nyeland ME, Laursen MV, Callreus T. Evaluating the effectiveness of risk minimisation measures: the application of a conceptual framework to Danish real-world dabigatran data. *Pharmacoepidemiol Drug Saf*. 2017 Jun;26(6):607-614.
  31. Callreus T, El-Galaly TC, Jerkeman M, Brown P, Andersen M. Monitoring CAR-T-Cell Therapies Using the Nordic Healthcare Databases. *Pharmaceut Med*. 2019 Apr;33(2):83-88.
  32. Mollebaek M, Kaae S, De Bruin ML, Callreus T, Jossan S, Hallgreen CE. The effectiveness of direct to healthcare professional communication - A systematic review of communication factor studies. *Res Social Adm Pharm*. 2019 May;15(5):475-482.
  33. Sessa M, Mascolo A, Callreus T, Capuano A, Rossi F, Andersen M. Direct-acting oral anticoagulants (DOACs) in pregnancy: new insight from VigiBase(R). *Sci Rep*. 2019 May 10;9(1):7236.
  34. El-Galaly TC, Cheah CY, Kristensen D, Hutchison A, Hay K, Callreus T, Villa D. Potentials, challenges and future of chimeric antigen receptor T-cell therapy in non-Hodgkin lymphomas. *Acta Oncol*. 2020 Jul;59(7):766-774.
  35. Jakobsen LH, Callreus T, Sessa M, Jerkeman M, Andersen M, El-Galaly TC. Detecting deviations from the efficacy and safety results of single-arm trials using real-world data: The case of a CAR-T cell therapy in B-cell lymphoma.

Pharmacoepidemiol Drug Saf. 2021 Apr;30(4):514-519.

36. Callreus T. The Randomised Controlled Trial at the Intersection of Research Ethics and Innovation. *Pharmaceut Med.* 2022 Oct;36(5):287-293.

37. Callreus T, Moghissi AA, Steen TY. Introduction to Regulatory Pharmacology. In: Steen TY, Moghissi AA, Calderone RA, Hamidi N, editors. *Introduction to Regulatory Science*. Newcastle upon Tyne: Cambridge Scholars Publishing; 2024. pp 356-384.

### Projects

Member of Work Package 5 (Benefit-risk integration and presentation) of the PROTECT Consortium, Innovative Medicines Initiative (2009-2011)

### Memberships

Member of the American Society for Clinical Pharmacology and Therapeutics

### Other Relevant Information

Member of the Editorial Board of "Pharmaceutical Medicine", Adis International Limited (2011-Present)