Partner Profile

The European Medicines Agency (EMA) is a decentralised agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union, including vaccines. The EMA is coordinating the European Network of Centres for Pharmacovigilance and Pharmacoepidemiology (ENCePP) which established methodological and ethical standards for pharmacoepidemiological studies, including a code of conduct. The EMA also coordinates scientific committees relevant for this project, including the Vaccine Working Party, the PRAC, the Patients and Consumers Working Party (PCWP) and the Health Care Professionals Working Party (HCPWP).It began operating in 1995.

Website: www.ema.europa.eu

Role in the ADVANCE Project

EMA will coordinate WP1 "Best practice and code of conduct for benefit-risk monitoring ofvaccines". Its main task will be to contribute to: a framework defining the roles and responsibilities of all relevant stakeholders in the infrastructure for vaccine impact monitoring, including regulatory authorities, public health authorities, European agencies, vaccine manufacturers, patients and health care professionals; development of a best practice for post-authorisation safety and efficacy studies for vaccines, in accordance with Directive 2001/83/EC and Regulation (EC) No 726/2004, ensuring also that results of studies conducted through the infrastructure are linked to the decision-making process; facilitation of collaborations between the consortium and relevant scientific committees, such as the Vaccine Working Party, the Pharmacovigilance Risk Assessment Committee, and public health advisory committees.

Key People

Xavier Kurz graduated in 1982 as a Medical Doctor at the University of Liege, Belgium. He specialised in Tropical Medicine and worked for several years in public health projects in Africa and Asia. He obtained a MSc (1991) and a PhD (1997) in Epidemiology and Biostatistics at McGill University, Montreal, Canada. He joined the Department of Pharmacology of the University of Liege, where he developed and conducted pharmacoepidemiological and pharmacoeconomic studies on vascular disorders and dementia. He joined the Belgian Centre for Pharmacovigilance (Ministry of Health) as scientific expert in 1995 and the Pharmacovigilance and Risk Management Sector of the European Medicines Agency (EMA) in

2005. He is ad-interim Head of the Monitoring & Incident Management Service. He is coordinator of the IMI PROTECT (Pharmacoepidemiological Research in Outcomes of Therapeutics by a European ConsorTium) project and Principal Scientific Advisor to the European Network of Centre for Pharmacoepidemiology and Pharmacovigilance (ENCePP).

Peter Arlett is Head of Pharmacovigilance at European Medicines Agency. He graduated in Medicine from University College London (1991). Is Member of the Royal College of Physicians (MRCP) of London since 2004 and Member of the Faculty of Pharmaceutical Medicine (MFPM) of the Royal College of Physicians of London (2002). He was Fellow of the Faculty of Pharmaceutical Medicine (FFPM) of the Royal College of Physicians of London (2007). He was Principal Administrator, Pharmaceuticals Unit, DG Enterprise and Industry, European Commission (2003-2008). UK delegate to the European Committee for Human Medicinal Products (CHMP) (2001-2003). Specialist Assessor and Manager, Medicines Control Agency (now MHRA) (1996-2001). He was Hospital Physician, UK NHS, UCL, Oxford, Hammersmith (to 1996).

Priya Bahri Priya Bahri has completed studies and a Ph.D. in pharmacy and epidemiology & biostatistics and has work experience in hospital and community pharmacy as well as in healthcare research and international development. Since 1996, she has been working at the European Medicines Agency (EMA), for the co-ordination of the EU pharmacovigilance system and, since 2009, as the lead for pharmacovigilance guideline development (EU GVP) and risk communication. In that role she collaborates closely with patient, healthcare professional, academic and industry organisations. Additionally, she is in charge of pharmacovigilance collaboration with WHO and other international partners, and has been member of ICH and CIOMS working groups, including the CIOMS-WHO working group on vaccine pharmacovigilance. She holds a certificate in strategic health communication from Johns Hopkins University, and is active in ISPE and ISOP as regards the integration of communication processes into risk assessment. She provides lectures and research advice to various universities, in particular Humboldt University (Master in Consumer Health Care) and the Utrecht WHO Collaborating Centre for Pharmaceutical Policy and Regulation.

Alessandro Spina is the Data Protection Officer of the European Medicines Agency where he has been working since 2009. In his current role, he provides legal assistance on all matters related to the application to of EU data protection legislation (Regulation EC 45/2001) in the pharmaceutical regulatory framework and acts as a liaison with the European Data Protection Supervisor. A dually qualified Italian and English lawyer, he is acting for EMA in court proceedings before the Court of Justice of the EU. Alessandro studied law at the University of Siena, Italy, in 2004 and obtained in 2005 a Master of Laws (LLM) from the University of Oxford, UK. In 2010, he was awarded a PhD in Law and Economics from the University of Siena. He has been a Visiting Scholar in the Faculty of Laws of the University of Toronto and a Post-Doc Researcher in Biotechnology and Law and a Visiting Lecturer in Administrative Law at the University of Milan.