Faculty

Professor Jeffrey Aronson, Reader in Clinical Pharmacology, Oxford University and Honorary Consultant Physician; past Editor-in-Chief of the British Journal of Clinical Pharmacology; President Emeritus of the British Pharmacological Society; co-inventor of the EIDOS/DoTS classification system for ADRs

Professor Ralph Edwards, Emeritus Professor of Medicine; Former Director of the WHO Drug Monitoring Centre, Uppsala; Past President of the International Society for Pharmacovigilance; and former ICH/CIOMS member

Dr. Nawab Qizilbash, Head of OXON; Honorary Senior Lecturer in Pharmacoepidemiology, London School of Hygiene and Tropical Medicine; Honorary Consultant Geriatrician, Hospital Cantoblanco, Madrid; Chair of Data Integration Group and member of Steering Group in ENCePP at EMA (former Director of Epidemiology, GSK, 1997-2005)

Marta Mariño, Director of PV, OXON (Former Head of PV, Schering Plough, Spain, 1985-2010)

Clinical Consultants

Further details

Who should attend:

- **Drug safety specialists**
- **Industry Pharmacoepidemiologists:** Non-medical epidemiologists involved in conducting epidemiological studies of potential ADRs and (a good refresher for) medical epidemiologists who have not practised medicine for some years
- **Others who may find the course of interest:** Regulatory Affairs/ Medical Affairs/ Investigators

Venue: Hotel NH Nacional. Paseo del Prado, 48. Madrid, Spain (opposite El Prado Museum)

Language: English

Social events: Organised visits will be available in the evenings to the Prado and Reina Sofia (exhibits Picasso's Guernica) museums, followed by typical spanish dinner and flamenco.

Registration: Places will be limited to permit adequate participation of attendees during the practicals.

Further details and registration at:

info@oxonepi.com

www.oxonepi.com

Tel: +34 913 459 395 / +44(0) 203 574 4617

oxon epidemiology

Medical ADRs: From first case to regulatory action

Second Course
6th - 8th May 2014
Madrid, Spain

6th—8th May 2014

Madrid

Course Overview

The assessment, management and investigation of potential ADRs identified through single case reports require a basic understanding of clinical medicine and pharmacology.

The course focuses on acquiring and using the knowledge of mechanisms, clinical features, diagnosis and the clinical investigation and management of major ADRs to correctly identify, classify, investigate, assess causality, conduct appropriate studies to establish causality and act accordingly. (This is NOT a course about case processing or regulations).

Practicals are an important element of the course and will enable delegates to:

1. Learn through individual case reports to investigate clinically and assess causality
2. Work through real cases from first report through to regulatory actions, charting the course of several ADRs in different organ systems using: case reports, disproportionality analysis, epidemiological studies, trials and non-clinical data, as appropriate.

Practicals will be guided by a distinguished European multi-disciplinary faculty experienced in ADRs:

- **Clinical pharmacologist – Professor Jeffrey Aronson**
- **ICH/CIOMS expert – Professor Ralph Edwards**
- **Clinical epidemiologist – Dr Nawab Qizilbash**
- **Specialist clinician in the organ system of the ADR**
- **Industry PV expert—Marta Mariño**

Learning Objectives

- Understand the mechanisms, clinical patterns, and clinical investigation and management of serious ADRs in major organ systems
- Understand the practical usefulness of EIDOS/DoTS compared with the type A-E system to assess ADRs for evaluating, classifying and assessing causality of individual ADRs - from its inventor
- Feel confident about interpreting cases through practice with clinical case histories and feedback
- Learn from past ADRs how to investigate and manage ADRs from first case report to regulatory actions

Topics at a glance

Keynote Lecture I: Classifying ADRs - Relevance to Pharmacovigilance
Professor Jeffrey Aronson, Oxford University

Keynote Lecture II: Diagnosis and Management of ADRs
Professor Ralph Edwards, Former Director of the WHO Drug Monitoring Centre, Uppsala

Immune Basis of Drug Hypersensitivity: *Dr. Carlos Blanco, Head, Department of Allergy, University Hospital La Princesa, Madrid*

Dermatological ADRs: *Speaker to be confirmed*

Gastrointestinal ADRs: *Professor Agustín Albillos, Professor of Gastroenterology, University of Alcalá, Madrid*

Haematological ADRs: *Speaker to be confirmed*

Hepatic ADRs: *Professor Raúl J. Andrade Bellido, Head, Department of Hepatology, University Hospital Virgen de La Victoria, Málaga*

Cardiac ADRs: *Professor Jeffrey Aronson, Honorary Consultant Physician, John Radcliffe Hospital, Oxford*

Neuro-psychiatric ADRs: *Dr. Jesús López Arrieta, Head of Geriatrics, University Hospital La Paz-Cantoblanco, Madrid*

Renal ADRs: *Dr. José Luño Fernández, Head, Department of Nephrology, University Hospital Gregorio Marañón, Madrid*

Ophthalmological ADRs: *Dr. Francisco J Muñoz Negrete, Head, Department of Ophthalmology Hospital Ramón y Cajal, Madrid*

Vaccine-related ADRs: *Speaker to be confirmed*

ADRs in Pregnancy: *Dr. Javier Plaza Arranz, Head,* Department of *Gynecology & Obstetrics Fundación Jiménez Díaz, Madrid*

Post-marketing Risk Management: *Professor Jeffrey Aronson, Oxford University*
Study Designs to Assess Causality Following ADR Reports: *Dr Nawab Qizilbash, Honorary Senior Lecturer in Pharmacoepidemiology, London School of Hygiene and Tropical Medicine*
Benefit-Risk Assessment: *Andy Maguire, Database Epidemiologist, OXON, London & Pharmacology Deprtment, Alcala University, Madrid*

Practical Interactive Sessions *with historical ADR cases:* guided by a panel of clinical pharmacologist, ICH expert, clinical epidemiologist and a clinical consultant of the relevant body system.

oxon epidemiology