The London School of Hygiene & Tropical Medicine is a world-leading centre for research and postgraduate education in public and global health, with 4,000 students and more than 1,000 staff working in over 100 countries. The School was recently named the world’s leading research-focused graduate school (Thomson Reuters / Times Higher Education) and has been cited as one of the world’s top universities for collaborative research.

Our mission is to improve health and health equity in the UK and worldwide; working in partnership to achieve excellence in public and global health research, education and translation of knowledge into policy and practice.

How to Apply
Applicants should complete the online application form available on the course webpage:
www.lshtm.ac.uk/study/cpd/scpp.html

Registry
London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E 7HT
UNITED KINGDOM

Telephone:  +44 (0)20 7299 4648
Fax:            +44 (0)20 7299 4656
Email:        shortcourses@lshtm.ac.uk
Website:  www.lshtm.ac.uk/study/cpd

Other Courses
Full details of other short courses available at the School may be obtained from the Registry at the above address.

Other related short courses include the following:
Epidemiological Evaluation of Vaccines (offered in July each year)
Practical Pharmacoepidemiology (offered in September each year).

Comments from Recent Students
The Course
• “All lecturers are very enthusiastic, interesting and knowledgeable. Makes the content fun and enjoyable.”
• “Very informative with good workshops and high quality teaching.”
• “Lecturers with extensive practical experience, will definitely recommend the course.”
• “Really enjoyed the workshops with examples to work through - made it easier to learn.”
• “Lecturers and workshops are of very high quality.”
• “Overall atmosphere - a fun way to learn, with stimulating interactive sessions.”
• “Some tough subjects dealt with in a very entertaining way which made them easier to understand.”
• “Teaching quality - leaders in the industry!”
• “Thank you, I enjoyed it very much and learned a lot.”

Specific Lectures
• The EMA and the EU risk management guideline:
  “Thoroughly enjoyed this talk and could have listened to more. Especially liked the RMP proposals.”
• Multivariable analysis and propensity scores:
  “Particularly enjoyed these lectures. I didn’t think it was possible to put something so difficult in such simple terms. Content, pitch, speed and delivery were wonderful.”
• Meta analysis of Randomized Trials:
  “Just like the Clinical Trials lecture, this was brilliant. Both these lectures have given me something that I’ll have to practice during my work to try to become proficient.”
• Critical appraisal of meta analysis:
  “First time I’ve got to grips with concept of meta analysis.”
• Structured examination of a response to an ADR alert:
  “The workshop was brilliant! Great way to demonstrate the applications and explain the difficulties in this field of work.”
• Case only design and analysis:
  “Excellent lecturer - topic not the easiest, but lecture kept lively with good examples. Good summary of the key message at the end.”
Further Information: www.lshtm.ac.uk/study/cpd

The challenge of maximising drug safety yet maintaining public confidence has become increasingly complex. Pharmaceutical companies are required to employ named members of staff responsible for pharmacovigilance. Health authorities grapple with the need to provide quality care whilst containing a burgeoning drug budget. Regulatory authorities must balance the potential benefits of new drugs with varying levels of suspicion of their potential harm.

This 30-week examined course in pharmacoepidemiology and pharmacovigilance addresses the increasing need for well informed professionals to work in all areas related to the assessment of drug safety and risk-benefit of drug use. It is an introductory course and should meet the needs of a wide variety of practitioners. The variety of backgrounds and the knowledge possessed by lecturers ensures that the course has a sound mixture of the theoretical and the practical issues surrounding drug safety.

Course Dates

The course dates for 2015/16 are: 9 November 2015 to 31 May 2016. The course is part-time and comprises 300 hours (approximately one day per week on average) which are spent as follows: 80 hours formal teaching and contact time, 120 hours self-directed study and 100 hours project work. Formal (face-to-face) teaching will take place in three blocks: 9 - 12 November 2015, 15 - 18 February 2016 and 11 - 14 April 2016. Participants will be allocated a personal academic advisor, who will give them guidance in writing their project. The course is followed by examinations taking place on 31 May 2016.

Course Content

The curriculum will provide an introduction to epidemiology, statistics, pharmacoepidemiology and health economics. It will also cover the historical and legal background to pharmacovigilance and pharmacoepidemiology, and pharmacological basis of ADEs, addressing ADE issues at individual and population levels. Students will gain an understanding of how pharmacoepidemiological principles and methods are applied to practical drug issues.

The course is accredited for continuing medical and pharmacy education purposes.

Who Should Apply?

The course is aimed at personnel concerned with the safe use of medicines, particularly in developed countries, including those working (or intending to work) in:

- the pharmaceutical industry who are involved in drug development, licensing and surveillance
- regulatory bodies who are involved in licensing and surveillance
- the health service who are involved in drug policy, and
- health policy decision-making agencies

Entry Qualifications

Applicants will normally have a science, biomedical or biostatistical background, hold a second class honours degree of a UK university (or equivalent) in a science, medical, statistical or related subject and will usually have some experience in the area. However, previous experience will be taken into account in all cases. A CV should be submitted with the application.

Applicants must have a good standard of written and spoken English. In certain cases the School may ask the applicant to provide evidence of a satisfactory standard of English.

Course Fee

The course fee is £4,885. This fee includes tuition, supervision and examination fees, but excludes accommodation and meals. The course fee must be paid in full by 9 October 2015. We regret that this fee cannot be paid in instalments.

The variety of backgrounds and the knowledge possessed by lecturers ensures that the course has a sound mixture of the theoretical and the practical issues surrounding drug safety. The teachers range from academic staff at the School, to eminent practitioners in the international pharmaceutical industry, regulatory authorities, and public health including:

- **Prof Stephen Evans** - Prof of Pharmacoepidemiology, LSHTM & Former President International Society for Pharmacoepidemiology
- **Prof Sir Michael Rawlins** - Chair, Medicines and Healthcare Products Regulatory Agency
- **Dr Peter Arlett** - Head of Pharmacovigilance and Risk Management, European Medicines Agency
- **Prof Tjeerd van Staa** - Professor of e-Health, Farr Institute

The aims of the course is to equip students with a basic understanding of the concepts and practice of pharmacoepidemiology and pharmacovigilance. By the end of the programme, students should be able to:

- demonstrate an understanding of, and critically evaluate, issues surrounding the risks and benefits of drug use in humans including the cause, manifestations and consequences of adverse drug effects (ADEs), the manner in which these are detected and monitored, and the related historic and legal frameworks
- be familiar with and compare fundamental statistical, economic and epidemiological concepts and methods
- gain an understanding of, and reflect critically upon, important pharmacoepidemiological concepts and methods and how these methods can be applied to specific drug issues and pharmaceutical risk management
- assess and critically analyse the results of pharmacoepidemiological studies (other investigators’), including critical appraisal of the study question, study design, methods and conduct, statistical analyses and interpretation

Course Organisers

Course Organisers: Ian Douglas and Sinéad Langan
Email: pepi@lshtm.ac.uk

Approach to Teaching and Examination

Teaching will include traditional lectures and seminar workshops during formal teaching, self-directed learning in between formal teaching and self-directed (but supervised) project work. Workshops will address topics such as designing a pharmacoepidemiological study, critical appraisal of published papers, and responding to a drug safety alert. The self-directed component will be facilitated by the provision of detailed course material. Students will be provided with a reading list pertinent to the course.

The course is examined through unseen written examinations and submission of a written project, the subject of which is determined by the course organiser and each student will be supported by an academic advisor.