# Professional Certificate in Pharmacoepidemiology & Pharmacovigilance



# Background

The global health 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

## The course

This intensive modular 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 individuals. 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 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 adverse drug events (ADE), addressing ADE issues at individual and population levels, and the application of pharmacoepidemiological principles and methods to practical drug issues.

## Course delivery

The course is organised into the following three Blocks, with the teaching for each Block delivered synchronously online during the following weeks:

- Block 1 (11 15 November 2024):
  Introduction to Pharmacoepidemiology
- Block 2 (3 -7 February 2025):
  Introduction to Pharmacovigilance
- Block 3 (24 28 March 2025):
  Intermediate Pharmacoepidemiology & Pharmacovigilance

Students can sign up for one, two, or three Blocks. Students who would like to be assessed in order to obtain a Professional Certificate (30 credits) must attend all three Blocks in addition to preparing a project (submitted in April/May) and taking an exam (in May/June).

Each Block consists of approximately 30 hours of formal teaching and contact time (via online synchronous teaching/group work). The full assessed course leading to a Professional Certificate (three Blocks plus project and exam) comprises 300 total hours, which are spent as follows: ~80 hours formal teaching and contact time, ~120 hours self-directed study, and ~100 hours project work.

Already know the basics? Our Real-World Evidence in Pharmacoepidemiology short course (Block 4) provides hands-on experience analysing and overcoming common sources of error when using real-world data.

# Teaching methods

Teaching for each Block will be delivered primarily via online synchronous teaching during each teaching week. This will include pre-recorded lectures from subject matter experts. Students and tutors will then interact in live Q&A sessions and workshops during the teaching week where students have the opportunity to apply and discuss concepts introduced in the pre-recorded content. Workshops will address topics such as designing a pharmacoepidemiological study, critical appraisal of published papers, developing risk management plans and responding to a drug safety alert. In addition to the prerecorded lectures, students will be provided with lists of helpful scientific papers, articles and other content to assist with learning.

For students who take the full assessed course leading to a Professional Certificate (three Blocks plus project and exam), there will also be self-directed learning in between the online synchronous teaching weeks in the form of completing a project and practice exams.

## Assessment

For students who take the full assessed course leading to a Professional Certificate (three Blocks plus project and exam), the assessment consists of submission of a written project (worth 40% of the total grade) and a written examination (worth 60% of the total grade). You must be awarded a pass grade for both to be awarded the Professional Certificate.

# Who should apply?

This introductory level course covers aspects of drug development, licensing, surveillance and policy, and is aimed at individuals who are working (or intending to work) on any of these aspects in the following sectors:

- the pharmaceutical industry
- NGOs
- regulatory bodies
- health services
- health policy decision-making agencies

## Key information



#### Course delivery

Online



#### **Programme Director**

Christopher Rentsch



#### Course fees

Per block:

£1,550 (full fee) £975 (students or charity status) £550 (LMICs)

Full assessed course leading to Professional Certificate:

£5,150 (full fee) £3,240 (students or charity status) £1,825 (LMICs)



#### Contact email

shortcourses@lshtm.ac.uk



#### Find out more and apply

www.lshtm.ac.uk/study/short-courses/ pharmacoepi-pharmacovigilance-london The London School of Hygiene & Tropical Medicine (LSHTM) is one of the world's leading public health universities. We have an annual research income of more than £190 million, and provide outstanding specialist education for our 4,700 postgraduate students.

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. We are committed to helping create a more healthy, sustainable and equitable world for everyone, because we believe our shared future depends on our shared health.

Our short, post-experience and specifically designed short courses provide the opportunity for intensive study in specialised topics. These courses are ideal if you want to refresh your skills and keep in touch with the latest research and knowledge in public and global health.

