

# PROGRAMME SPECIFICATION

LONDON  
SCHOOL of  
HYGIENE  
& TROPICAL  
MEDICINE



## 1. Overview

<b>Academic Year (student cohorts covered by specification)</b>	2023-24
<b>Programme Title</b>	Professional Certificate in Pharmacoepidemiology and Pharmacovigilance
<b>Programme Director</b>	TBD
<b>Course Organisers</b>	Angel Wong, Christopher Rentsch, John Tazare, Kevin Wing, Laurie Tomlinson
<b>Awarding Body</b>	University of London
<b>Teaching Institution</b>	London School of Hygiene & Tropical Medicine
<b>Faculty</b>	Epidemiology and Population Health
<b>Length of Programme (months)</b>	7 months, part time (3 x 1 week modules offered annually) Professional certificate can be obtained once all 3 modules have been completed (plus exam and project).
<b>Entry Routes</b>	Professional Certificate (Level 7) based on completion of all 3 modules, exam and project. Individual modules can be completed standalone (non credit-bearing).
<b>Exit Routes</b>	Professional Certificate (Level 7) based on completion of all 3 modules, exam and project. Individual modules can be completed standalone (non credit-bearing).
<b>Award Titles</b>	Professional Certificate in Pharmacoepidemiology and Pharmacovigilance (upon completion of all 3 modules, exam and project) (30 credits at level 7)
<b>Accreditation by Professional Statutory and Regulatory Body</b>	Royal College of Physicians (20 CPD credits per short course <i>applied for</i> )
<b>Relevant PGT <a href="#">QAA Benchmark</a></b>	

<a href="#">Statement and/or other external/internal reference points</a>	No relevant PGT QAA benchmark for this programme			
<b>Level of programme within the Framework for Higher Education Qualifications (FHEQ)</b>	Postgraduate, Level 7			
<b>Total Credits</b>	<b>CATS:</b>	30	<b>ECTS:</b>	15
<b>HECoS Code</b>	100246;100260; 100270; 101049; 101317			
<b>Mode of Delivery</b>	Online synchronous teaching during teaching weeks, self-directed learning between teaching weeks (for those taking the full certificate).			
<b>Mode and Period of Study</b>	Part time			
<b>Cohort Entry Points</b>	Modules delivered in November, February and March			
<b>Language of Study</b>	English			
<b>Re-sit Policy</b>	<a href="https://www.lshtm.ac.uk/sites/default/files/academic-manual-chapter-08a.pdf">https://www.lshtm.ac.uk/sites/default/files/academic-manual-chapter-08a.pdf</a>			
<b>Extenuating Circumstances Policy</b>	<a href="https://www.lshtm.ac.uk/sites/default/files/academic-manual-chapter-07.pdf">https://www.lshtm.ac.uk/sites/default/files/academic-manual-chapter-07.pdf</a>			
<b>Programme Description</b>	<p>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. NGOs need to have confidence that the medicines and products that they provide to communities are both effective and safe. 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.</p> <p>This intensive modular course in pharmacoepidemiology and pharmacovigilance addresses the increasing need for well-informed</p>			

	<p>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.</p> <p>The course is organised into the following three Blocks, with the teaching for each Block delivered synchronously online during the following weeks:</p> <ul style="list-style-type: none"> <li>- Block 1 (Nov): Introduction to Pharmacoepidemiology</li> <li>- Block 2 (Feb): Introduction to Pharmacovigilance</li> <li>- Block 3 (Mar): Intermediate Pharmacoepidemiology &amp; Pharmacovigilance</li> </ul> <p>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 May) and taking an exam (in June).</p> <p>Each Block consists of approximately 27 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.</p>
<p><b>Date of Introduction of Programme (month/year)</b></p>	<p>November 2006</p>
<p><b>Date of production / revision of this programme specification (month/year)</b></p>	<p>August 2022</p>

## 2. Programme Aims & Learning Outcomes

### **Educational aims of the programme**

The aim of the programme – consistent with LSHTM's mission to improve health worldwide – is to equip students with a thorough understanding of the concepts and practice of pharmacoepidemiology and pharmacovigilance.

### **Programme Learning Outcomes**

By the end of the three courses, students should be able to:

#### **Modules 1 and 3:**

- i) Describe the main study designs used in pharmacoepidemiology and their strengths and weaknesses.
- ii) Demonstrate an understanding of the epidemiological and statistical theory underpinning the conduct, analysis, reporting and interpretation of epidemiological studies.  
Critically assess the results of pharmacoepidemiology studies, including the study question, study design, methods and conduct, statistical analyses and interpretation.
- iii) Appraise meta-analyses and studies using multiple data sources or study designs

#### **Modules 2 and 3:**

- iv) Demonstrate an understanding of the legislation and regulations for pharmacovigilance and pharmacoepidemiology activities in the UK and internationally.
- v) Gain a thorough understanding and reflect critically upon the role of spontaneous reporting in pharmacovigilance.
- vi) Critically apply understanding the key principles of Health Technology Appraisal.
- vii) Apply pharmacoepidemiology evidence to decision making, risk management planning and responses to adverse drug events

### **Teaching and Learning Strategy**

The programme will be taught online through lectures and small group practicals. All elements of the programme have specific learning objectives, with content designed to help students achieve these outcomes. Students are expected to learn through both directed and self-directed study.

### **Assessment Strategy**

During the course there are a number of formative assessments such as interactive workshops. These assessments aim to monitor the study progress of the students; therefore, they do not contribute to the final mark of the course.

The summative assessment is conducted via an unseen written examination and a project.

The unseen written examination comprises two parts – one short-answer examination (75% of the unseen examination grade) and one multiple-choice examination (25% of the unseen examination grade). This examination will comprise 60% of the final mark for the Certificate.

The project will make up 40% of the final mark for the Certificate. The project report will be judged on the students' appreciation of the issues, their ability to make a critical evaluation of the evidence, and the appropriateness and justification of their recommendations.

Both the unseen examination and the project need to be passed in order to pass the Professional Certificate.

### **3. Programme Structure and features, modules, credit assignment and award requirements**

<b>Full-time Masters</b>	<b>Term 1</b>	<b>Term 2</b>	<b>Term 3</b>	<b>Total Credits</b>
Compulsory Modules	1			30
Recommended Modules				N/A
Projects				N/A

<b>Term</b>	<b>Module Code</b>	<b>Module Title</b>	<b>Module Type (compulsory or recommended)</b>	<b>Credits (CATS)</b>	<b>Contact hours</b>
1, 2 and 3	n/a	Professional Certificate in Pharmacoepidemiology and Pharmacovigilance	Compulsory	30	84

## 4. Entry Requirements

### Criteria for admission

There are no formal prerequisites for this course, but some experience equivalent to the followed is required:

- an undergraduate degree (e.g., bachelor) in a subject appropriate to the course (e.g., epidemiology, statistics, pharmacy, biological sciences, chemistry, physics, medicine, dentistry, etc.); or
- in exceptional circumstances requiring pre-approval from the course organisers, at least 6 months' relevant work experience; and
- applicants should have a good command of English.

If students do not satisfy the above requirements they may still be admitted at the course organisers discretion on the basis of their academic qualifications, work experience and references.

### English language entry requirements

#### Band B

It is essential that all students have a good command of the English language to benefit from their studies at the LSHTM.

As part of the application process, applicants are required to demonstrate how they meet the LSHTM's minimum English language requirements. For the Professional Certificate in Pharmacoepidemiology and Pharmacovigilance we require band B or above, or level C with extensive recent experience in an English-speaking setting.

For information, please refer to the LSHTM English Language Requirement Policy:

[https://www.lshtm.ac.uk/sites/default/files/english\\_language\\_requirements\\_policy.pdf](https://www.lshtm.ac.uk/sites/default/files/english_language_requirements_policy.pdf)