PROGRAMME SPECIFICATION



1. Overview

Academic Year (student cohorts covered by specification)	2022-23	
Programme Title	Professional Certificate in Pharmacoepidemiology and Pharmacovigilance	
Programme Director	Kevin Wing, Rohini Mathur, Anna Schultze, Laurie Tomlinson, Angel Wong	
Awarding Body	University of London	
Teaching Institution	London School of Hygiene & Tropical Medicine	
Faculty	Epidemiology and Population Health	
Length of Programme (months)	7 months, part time	
Entry Routes	Professional Certificate	
Exit Routes	Professional Certificate	
	Certificate of Attendance and CPD Credits	
Award Titles	Professional Certificate in Pharmacoepidemiology and Pharmacovigilance (30 credits at level 7)	
Accreditation by Professional Statutory and Regulatory Body	Royal College of Physicians (20 CPD credits per short course <i>applied for</i>)	
Relevant PGT QAA Benchmark Statement and/or other external/internal reference points	No relevant PGT QAA benchmark for this programme	
Level of programme within the Framework for Higher Education	Postgraduate, Level 7	

Qualifications (FHEQ)					
Total Credits	CATS: 30 ECTS: 15				
HECoS Code	100246;1002	260; 100270;	101049; 101317	7	
Mode of Delivery	We are planning for our courses in 2022/23 to be delivered through predominantly in-person teaching on campus combined with elements of online delivery. Our students will be expected to be in London for the duration of their programme, attending classes in person throughout the year.				
Mode and Period of Study	Part time				
Cohort Entry Points	Short courses delivered in December, February and April				
Language of Study	English				
Re-sit Policy	https://www.lshtm.ac.uk/sites/default/files/academic- manual-chapter-08a.pdf				
Extenuating Circumstances Policy	https://www.lshtm.ac.uk/sites/default/files/academic- manual-chapter-07.pdf				
Programme Description	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 aburgeoning drug budget. Regulatory authorities must balance the potential benefits of new drugs with varying levels of suspicion of their potential harm. This intensive modular course in pharmacoepidemiology and pharmacovigilance addresses the increasing need for well-informed				
	professional assessment use. It is an i	s to work in a of drug safet ntroductory	all areas related y and risk-bene course and sho f individuals. Th	to the fit of drug uld meet the	

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. This course is offered in amodular format across three short courses and delivered via acombination of face-to-face and online teaching modes. Short course 1 covers 'Introduction to Pharmacoepidemiology', Short course 2covers 'Introduction to Pharmacovigilance' and Short course 3 covers 'Intermediate Pharmacoepidemiology & Pharmacovigilance'. Students can either apply for all three short courses (with or without assessment), or alternatively to any selection of the individual courses (without assessment). Students who complete all three short courses and the assessment within one academic year will be awarded a Professional Certificate (30 credits). **Date of Introduction** November 2006 of Programme (month/year) Date of production / November 2021 revision of this programme

2. Programme Aims & Learning Outcomes

Educational aims of the programme

specification
(month/year)

The aim of the programme – consistent with LSHTM's mission to improve health worldwide –is to equip students with athorough 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:

Short course 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

Short course 2 and 3:

- iv) Demonstrate an understanding of the legislation and regulations for pharmacovigilance and pharmacoepidemiology activities in the UK and internationally.
- v) Gain athorough 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 acritical 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

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

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

4. Entry Requirements

Criter		

There are no formal prerequisites for this course, but some experience equivalent to the followed is required: an undergraduate degree (e.g., bachelor) in asubject appropriate to the course (e.g., epidemiology, statistics, pharmacy, biological sciences, chemistry, physics, medicine, dentistry, etc.); or at least 6months' relevant work experience. If you do not satisfy the above requirements you may still be admitted at our discretion on the basis of your academic qualifications, work experience and references.

English language entry requirements

Band B

It is essential that all students have agood 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_po_licy.pdf