



1. Overview

Academic Year (student cohorts covered by specification)	2019/20			
Programme Title	Pharmacoepidemiology and Pharmacovigilance			
Programme Director	Sinead Langan, Kevin Wing, Rohini Mathur			
Awarding Body	University of London			
Teaching Institution	London School of Hygiene & Tropical Medicine			
Faculty	Epidemiology and Population Health			
Length of Programme (months)	Professional Certificate – part time = 8 months			
Entry Routes	Professional Certificate (Level 7)			
Exit Routes	Professional Certificate (Level 7)			
Award Titles	Professional Certificate in Pharmacoepidemiology and Pharmacovigilance			
Accreditation by Professional Statutory and Regulatory Body	N/A			
Relevant PGT QAA Benchmark Statement and/or other external/internal reference points	Not applicable			
Level of programme within the Framework for Higher Education Qualifications (FHEQ)	Postgraduate, Level 7			
Total Credits	CATS:	30	ECTS:	15
HECoS Code	tbc			
Mode of Delivery	'Face-to-face' at LSHTM in London			
Mode and Period of Study	Part time			
Cohort Entry Points	Annually in November			
Language of Study	English			
Re-sit Policy	https://www.lshtm.ac.uk/sites/default/files/Resits_Policy_Policy_Procedure.pdf			
Extenuating Circumstances Policy	https://www.lshtm.ac.uk/edu/taughtcourses/exams_assmt_staff/extenuating_circumstances_policy.pdf			
Programme Description	The global health challenge of maximising drug safety yet maintaining public confidence has become increasingly complex.			

	<p>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.</p> <p>This 30-week examined training 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.</p> <p>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.</p>
Date of Introduction of Programme (month/year)	November 2006
Date of production / revision of this programme specification (month/year)	June 2018

2. Programme Aims & Learning Outcomes

Educational aims of the programme
<p>The aim of the programme – consistent with LSHTM's mission to improve health worldwide – 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:</p> <ul style="list-style-type: none"> i) Demonstrate an understanding and evaluate critically 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 ii) Be familiar with and compare fundamental statistical, economic and epidemiological concepts and methods iii) Gain an understanding of and reflect critically upon important pharmacoepidemiological concepts and methods and how these methods can be applied to specific drug issues iv) 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
Programme Learning Outcomes
<p>By the end of the programme, students will be expected to achieve the following learning outcomes – drawing on material taught across different elements and assessed in a variety of ways.</p> <ul style="list-style-type: none"> i) Demonstrate a thorough knowledge and understanding and critically evaluate the main study designs used in pharmacoepidemiology and their strengths and weaknesses; ii) Demonstrate a basic understanding of the epidemiological and statistical theory underpinning the conduct, analysis, reporting and interpretation of epidemiological studies; iii) Critically assess the results of pharmacoepidemiology studies, including critical appraisal of the study question, study design, methods and conduct, statistical analyses and interpretation; iv) Appreciate and reflect critically upon how the legislative/regulatory landscape shapes core pharmacovigilance and pharmacoepidemiology activities; v) Gain a thorough understanding and reflect critically upon of the role of spontaneous reporting in pharmacovigilance; vi) Acquire awareness and critical reflection of the key principles of Health Technology Appraisal.

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 Pharmacoepidemiology and Pharmacovigilance	Compulsory	30	100

4: Entry Requirements

Criteria for admission
<p>Applicants must normally satisfy LSHTM's general entrance requirements and additional programme specific entrance requirements to be considered for admission. Applications must be submitted in accordance with the procedures and deadlines given in the web-based or printed prospectus.</p> <p>In order to be admitted to this programme of the London School of Hygiene & Tropical Medicine, an applicant must:</p> <ul style="list-style-type: none"> a) hold a first degree at Second Class Honours standard in a relevant discipline, a degree in medicine at the same standard, or another degree of equivalent awarded by an overseas institution recognised by UK Naric or Barrons. <p>OR</p> <ul style="list-style-type: none"> b) hold a professional qualification appropriate to the programme of study to be followed obtained by written examinations and judged by the School to be equivalent to a Second Class Honours degree or above. <p>OR</p> <ul style="list-style-type: none"> c) have relevant professional experience or training which is judged by the School to be equivalent to a Second Class Honours degree or above. <p>AND</p> <p>satisfy any additional requirements where prescribed for admission to a specific programme.</p>

English language entry requirements
<p>Band B</p> <p>It is essential that all students have a good command of the English language to benefit from their studies at the School.</p> <p>As part of the application process, applicants are required to demonstrate how they meet the School's minimum English language requirements. This is particularly important for applicants requiring a Tier 4 Student visa, as the UK Home Office dictates that every student from outside the UK and European Union (EU) must show evidence of a minimum level of English language ability (called CEFR1 B2 level), in order for a Tier 4 Student visa to be issued for entry to the UK.</p> <p>Additionally, the School asks applicants to have minimum English language proficiency levels that are necessary for our academic programmes. These levels are higher than the CEFR B2 minimum level and also apply to EU applicants, although these will not normally require a Tier 4 Student visa.</p> <p>The academic English language requirements for each of the School's programmes are categorised into one of three profiles A, B or C. For information on these three profiles, please refer to the LSHTM English Language Requirement Policy: https://www.lshtm.ac.uk/files/english-language-requirements.pdf</p>