PROGRAMME SPECIFICATION

1. Overview

Academic Year (student cohorts covered by specification)	2023-24
Programme Title	Professional Certificate in Pharmacoepidemiology and Pharmacovigilance
Programme Director	Christopher Rentsch
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 (3 x 1 week teaching Blocks offered annually) Professional Certificate will be obtained once all 3 Blocks have been completed and both Project and Exam have been passed.
Entry Routes	Professional Certificate (Level 7) based on completion of all 3 Blocks and passing of the Project and Exam. Individual Blocks can be completed standalone without Assessments (non credit-bearing).
Exit Routes	Professional Certificate (Level 7) based on completion of all 3 Blocks and passing of the Project and Exam. Individual Blocks can be completed standalone without Assessments (non credit-bearing).
Award Titles	Professional Certificate in Pharmacoepidemiology and Pharmacovigilance (Cert P Epi & P Vig)
Accreditation by Professional Statutory and Regulatory Body	N/A
Relevant PGT QAA Benchmark Statement and/or other	No relevant PGT QAA benchmark for this programme

external/internal reference points	
Level of programme within the Framework for Higher Education Qualifications (FHEQ)	Postgraduate, Level 7

Total Credits	**CATS:**	30	**ECTS:**	15

HECoS Code	100246;100260; 100270; 101049; 101317
Mode of Delivery	Online synchronous teaching during teaching blocks (for all students) Self-directed learning between teaching blocks (for those taking the full Professional Certificate).
Mode and Period of Study	Part-time
Cohort Entry Points	Modules delivered in November, February, and March
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 a burgeoning 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

| | 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.

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

- Block 1 (Nov): Introduction to Pharmacoepidemiology
- Block 2 (Feb): Introduction to Pharmacovigilance
- Block 3 (Mar): 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 at level 7) must attend all three blocks in addition to passing a project and exam (typically submitted in May/June).

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. |
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| **Date of Introduction of Programme (month/year)** | November 2006 |
| **Date of production / revision of this programme specification (month/year)** | August 2023 |

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 teaching blocks, students should be able to:
 	
Blocks 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.
   iii)   Critically assess the results of pharmacoepidemiology studies, including the study question, study design, methods and conduct, statistical analyses and interpretation.
   iv)   Appraise meta-analyses and studies using multiple data sources or study designs.
 	
Blocks 2 and 3:
   v)   Demonstrate an understanding of the legislation and regulations for pharmacovigilance and pharmacoepidemiology activities in the UK and internationally.
   vi)   Gain a thorough understanding and reflect critically upon the role of spontaneous reporting in pharmacovigilance.
   vii)   Critically apply understanding the key principles of Health Technology Appraisal.
   viii)   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, peer group critical appraisals, project practice, and exam practice. These assessments aim to monitor the study progress of the students; therefore, they do not contribute to the final mark of the course.

There are two overall assessed components which contribute to the award of the Professional Certificate. These are as follows:

- Project: 40% of the overall grade which comprises an academic, research-based project.
- Exam: 60% of the overall grade which comprises a short question examination

The aim of the project is to demonstrate skills in critical assessment and evaluation related to a relevant topic in the field. Students will be provided with five papers in relation to this topic and will be required to critically assess them and come up with conclusions and recommendations. The project requires students to use techniques and approaches covered in the course, plus their own experience, to develop recommendations for the best option or options. The project report should evaluate the papers provided, assess the strengths and weaknesses of the evidence, and derive recommendations for action based on assessment of the evidence.

The exam will consist of multiple short answer questions (SAQs), covering topics including, but not limited to:
- Study design
- Adverse drug reactions & risk/benefit
- Confounding & effect modification
- Health economics
- Risk management and minimisation
- Statistical and clinical significance
- Spontaneous reporting, disproportionality
- Measures of effect
- Selection bias & misclassification
- Systematic reviews

Both the project and exam need to be passed in order to be awarded the Professional Certificate in Pharmacoepidemiology and Pharmacovigilance (Cert P Epi & P Vig).

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	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 course, we require Band B or above, or Band 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