PROGRAMME SPECIFICATION

1. Overview

Programme Title	Professional Certificate in Pharmacoepidemiology and Pharmacovigilance
Academic Year	2027-28
Cohort Entry Points	Teaching Blocks typically delivered in November, February, and March
Programme Director	Christopher Rentsch
Awarding Body	London School of Hygiene & Tropical Medicine
Teaching Institution	London School of Hygiene & Tropical Medicine
Faculty	Epidemiology and Population Health
Length of Programme	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.
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).
Maximum period of registration	Part-time 2 years
Language of Study	English
Entry Requirements	Please refer to the specific programme entry requirements here.
Award Titles	Professional Certificate in Pharmacoepidemiology and Pharmacovigilance (Cert P Epi & P Vig)
Total Credits	**CATS:** 30 **ECTS:** 15
Accreditation by Professional	None

Statutory and Regulatory Body	
Relevant PGT QAA Benchmark Statement and/or other external/internal reference points	Consistent with the Framework for Higher Education Qualifications at Masters level (level 7)
Framework for Higher Education Qualifications Level (FHEQ)	Level 7
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
Date of Introduction of Programme	November 2006

2. Programme Description, Aims & Learning Outcomes

Programme Description
The global health challenge of ensuring drug safety while maintaining public confidence has become increasingly complex. Pharmaceutical companies must employ dedicated pharmacovigilance professionals. NGOs need confidence that the medicines they supply are both effective and safe. Health authorities must deliver high-quality care while managing costs. Regulatory bodies must weigh the benefits of drugs against concerns about potential harms. This intensive, modular course addresses the growing demand for professionals trained in assessing drug safety and evaluating the risks and benefits of drug use. As an introductory-level course, it is designed to meet the needs of a wide range of individuals. The diverse backgrounds and expertise of our lecturers ensure a strong balance of theoretical insight and practical applications.

The course is organised into three blocks taught across one week each :

- Block 1: Introduction to Pharmacoepidemiology
- Block 2: Introduction to Pharmacovigilance
- Block 3: Intermediate Pharmacoepidemiology & Pharmacovigilance

To obtain the full Professional Certificate (30 Level 7 credits), students must:

- Complete all three blocks.
- Submit a 5000-word written Project critically appraising a potential drug safety signal (40% of the total grade).
- Take a 2-hour written Exam of short answer questions (60% of the total grade).

Not ready to commit to the full course? Students can register for individual blocks without assessment. If desired, they may later upgrade to the full Professional Certificate pathway.

Students may complete the full Professional Certificate course within one academic year or spread it across two consecutive years.

Each block consists of ~28 hours of formal teaching and contact time. The full Professional Certificate pathway requires ~300 total hours:

- ~80 hours of formal teaching and contact time.
- ~120 hours of self-directed study.
- ~100 hours to complete the Project.

Educational aims of the programme

This well-established training programme equips students with a basic understanding of the concepts and practice of pharmacoepidemiology and pharmacovigilance. By the end of the programme, you will be able to:

- Demonstrate an understanding of, and critically evaluate, issues surrounding the risks and benefits of drug use in humans. This includes the cause, manifestations, and consequences of adverse drug effects (ADEs), how these are detected and monitored, and the related historic and legal frameworks.
- Compare fundamental statistical, economic, and epidemiological concepts and methods.
- Understand and reflect upon important pharmacoepidemiological concepts and methods, and how these methods can be applied to specific drug issues and pharmaceutical risk management.

Critically appraise the results of published pharmacoepidemiological studies, including a critical appraisal of the research question, study design, methods, statistical analyses, and interpretation.

Programme Learning Outcomes

By the end of Block 1, students should be able to:

- Describe the main study designs used in pharmacoepidemiology and understand their strengths and limitations.
- Demonstrate a basic understanding of the epidemiological and statistical theory underpinning the conduct, analysis, reporting, and interpretation of pharmacoepidemiological studies.
- Critically assess key components of published pharmacoepidemiological studies, including the research question, study design, methods, statistical analysis, and interpretation.

By the end of Block 2, students should be able to:

- Appreciate and reflect critically upon the impact of regulatory frameworks on pharmacovigilance activities in the UK and internationally.
- Understand the role and limitations of spontaneous reporting in pharmacovigilance.
- Evaluate key principles of Health Technology Appraisal.

By the end of Block 3, students should be able to:

- Understand confounding and interaction and their implications for study design and interpretation.
- Assess compliance of studies with STROBE/RECORD reporting standards.
- Understand key approaches to handling confounding, including multivariable regression, propensity scores, and case-only designs.
- Critically appraise meta-analyses and studies using multiple data sources or study designs.
- Apply pharmacoepidemiological evidence to regulatory decision making, risk management planning, and responses to adverse drug events.

Teaching and Learning Strategy

All teaching will be delivered online and consists of:

- Self-study materials (e.g., pre-recorded lectures, Between-Block activities).
- Synchronous live sessions (e.g., Q&A, group discussions, practical sessions).

Each block is tentatively set to run 9:30-17:00 UK time daily, with morning and afternoon sessions spread over five days. This includes time to work through the self-study materials. Synchronous live sessions provide students the

opportunity to apply and discuss concepts introduced in the self-study materials.

While attending all live sessions is not mandatory, students who attend tend to achieve the best results. Most lectures are pre-recorded and made available on the course website one week prior to each block. Some lectures are delivered live, and these are also recorded and uploaded to the course website within 24 hours. Live sessions (except for practicals) will be recorded and made available to students within 24 hours. Practicals will not be recorded; however, solution sets to all practicals are made available immediately following each practical to allow students to work through the materials in their own time. Students can access an online forum on the course website to post questions about any of the course materials to the course tutors during the course.

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:

- A 5000-word written Project critically appraising a potential drug safety signal (40% of the total grade).
- A 2-hour written Exam of short answer questions (60% of the total grade).

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 up to 4 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.

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

Full-time Masters	Term 1	Term 2/3	Term 3	Total Credits
Compulsory Modules	1			30
Recommended Modules				N/A
Project				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 Pharmaco-epidemiology and Pharmacovigilance	Compulsory	30	84

Contact time

Student contact time refers to the tutor-mediated time allocated to teaching, provision of guidance and feedback to students. This time includes activities that take place in face-to-face contexts such as on-campus lectures, seminars, demonstrations, tutorials, supervised laboratory workshops, practical classes, project supervision and external fieldwork or visits, as well as where tutors are available for one-to-one discussions and interaction by email. Module contact time will be defined in the individual module specifications and provided to students at the start of their programme.

This definition is based on the one provided by the Quality Assurance Agency for Higher Education (QAA) Explaining contact hours (2011). Student contact time, together with time allocated for independent study and assessment, determines the total student study hours for a module or programme. Although there are separate hours allocated for each of these activities, they should always be clearly linked together to support effective learning.
The London School of Hygiene and Tropical Medicine (LSHTM) defines high quality contact time as structured, focused, purposeful and interactive.