



**UNIVERSITY
OF LONDON**

Programme Specification 2021–2022

Pharmacoepidemiology and Pharmacovigilance

Postgraduate individual module

Important document – please read



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& TROPICAL
MEDICINE



Alternative Assessments during the Coronavirus (COVID19) Outbreak

In line with our current General Regulations, the University may offer you alternative assessments where necessary. This includes holding online timed assessments in place of written examinations, which are usually held at examination centres. Please note that this statement replaces any published information relating to assessments or written examinations in any of our materials including the website. Previously published materials relating to examinations should therefore be read in conjunction with this statement.

The University of London continues to work towards supporting the academic progression of all its students. The University also continues to be mindful of the health and wellbeing of its students during this pandemic, whilst protecting the academic standards of its awards.



SHORT COURSE MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2021-22
Module Code	PCM100
Module Title	Postgraduate Professional Development course in Pharmacoepidemiology and Pharmacovigilance
Module Organiser(s)	Luigi Palla and Angel Wong
Faculty	Epidemiology and Population Health London School of Hygiene & Tropical Medicine
FHEQ Level	Level 7
Credit Value	CATS 30 ECTS 15
HECoS Code	n/a
Mode of Delivery	Distance Learning
Mode of Study	Directed self-study, through online materials via the Virtual Learning Environment
Language of Study	English
Pre-Requisites	None
Accreditation by Professional Statutory and Regulatory Body	None
Module Cap (Maximum number of students)	None
Target Audience	If you are working in the pharmaceutical industry or the drug regulatory authorities then this course may be of interest to you.
Module Description	This course covers the fundamentals of pharmacoepidemiology, its conduct, practical uses and limitations in determining the effects of medications in large



	<p>groups of people. The statistical basis underpinning pharmacoepidemiology will also be introduced, stimulating students to integrate statistics and epidemiology to gain competence in critically appraising pharmacoepidemiology studies. Further, key elements of pharmacovigilance and its basis within drug regulation will be presented and, within the risk management elements of the course, students will gain insight into how pharmacoepidemiology and pharmacovigilance are combined in the investigation of the effects of medicines.</p>
Duration	<p>Students may access the online study materials at any time from 1 November and work through the material until the start of the June examinations.</p> <p>Tutorial support for this distance learning module is available from the beginning of November through to the end of May.</p>
Entrance requirements	<p>Applicants will normally have a science, biomedical or biostatistical background, hold a second-class honours degree of a United Kingdom university (or equivalent) in a science, medical, statistical or related subject (e.g. biological sciences, chemistry, physics, medicine, dentistry, pharmacy, statistics) and will have some experience in the area.</p> <p>However, previous experience will be taken into account in all cases (e.g. working in a pharmaceutical company or drug regulatory authority for at least six months, in a scientific role).</p>
Student selection	<p>Students will be selected based on meeting the entrance requirements specified above. This module is available to be studied by students who are interested in studying a Postgraduate Professional Development course in Pharmacovigilance and Pharmacoepidemiology.</p> <p>This module is also open to LSHTM research degree students.</p>
Fees	<p>The fee for this short course will be £4,260 in 2021-2022 payable in one instalment to the University of London prior to the start of the course.</p>
Last Revised (e.g. year changes approved)	<p>November 2020</p>

Module Aim and Intended Learning Outcomes

Overall aim of the module

The overall module aim is to:

- equip students with a basic understanding of the concepts and practice of pharmacoepidemiology and pharmacovigilance, and to apply these skills to a currently unresolved drug safety issue.

Module Intended Learning Outcomes

Upon successful completion of the module a student will be able to:

1. be able to demonstrate an understanding and critically evaluate 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;
2. be able to understand and critically compare fundamental statistical, economic and epidemiological concepts and methods;
3. gain an understanding of and reflect critically upon important pharmacoepidemiological concepts and methods and how these methods can be applied to specific drug issues;
4. be able to assess and critically analyse the results of pharmacoepidemiological studies, including critical appraisal of the study question, study design, methods and conduct, statistical analyses and interpretation;
5. understand how new medicines are assessed for their cost-effectiveness as well as efficacy and safety, before being recommended for use;
6. be able to use the techniques and approaches covered in the taught element of the module, plus their own experience, to evaluate issues presented to them in the format of a project, and, where relevant, develop recommendations for the best option or options.



Indicative Syllabus

Teaching and Learning

Notional Learning Hours

Type of Learning Time	Number of Hours	Expressed as Percentage (%)
Directed self-study	100	33%
Self-directed learning	60	20%
Assessment, review and revision	140	47%
Total	300	100%

Teaching and Learning Strategy

Learning is self-directed against a detailed set of learning objectives using the materials provided. Students are strongly encouraged to participate in the module-specific discussions and real-time tutorials available on Moodle to obtain tutor support, and to make use of LSHTM online library resources. In addition, written feedback is provided on submitted assignments.

For the project, learning is self-directed against a detailed set of learning objectives using the materials provided. The course tutors will provide guidance and feedback through the relevant forums. They are not there to re-explain concepts covered in the module, to teach extra material, or to proof-read material that will be submitted for assessment. Additionally the course tutors will provide feedback on a brief written submission midway through the project.

In particular, the project will require about 100 hours, approximately divided as follows:

Self-directed learning (*Project only*)

Background reading: 4 hours

Note-making/consolidation: 32 hours

Online (Moodle) discussions: 4 hours

Assessment, review, revision (*Project only*)

Preparation and writing of interim summary/Report: 50 hours

Student-led academic adviser guidance and feedback: 10 hours



Assessment

Assessment Strategy

During the course there are a number of formative assessments including exercises, interactive workshops and exam practices. These assessments are aimed 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 module. The project will make up 40% of the final mark for the module. 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 with a grade of 50% or more in order to pass the module.

Summative Assessment

Assessment Type	Assessment Length (i.e. Word Count, Length of presentation in minutes)	Weighting (%)	Intended Module Learning Outcomes Tested
Exam	One short-answer examination (75%) and one multiple-choice examination (25%).	60%	1,2,3,4 and 5
Project	4,000 words	40%	1,2,3,4 and 6



The unseen examination for this module, PCM100, will coincide with the written examinations for the in-house LSHTM PEPI course, which are held once a year, in June (including resits).

Examinations will be taken in a student's country of residence, in one of over 650 examination centres worldwide (arranged mainly through Ministries of Education or the British Council).

A list of examination centres can be found [here](#).

A local fee will be payable direct to the examination centre. This fee is in addition to the course/module fee and is set by, and paid directly to, the individual examination centres. The level of local examination centre fees varies across the world and neither the University of London nor the LSHTM have any control over the fee amount.

For the project there are two milestones to be met:

February: Submission of a brief interim summary of work on the project

May: Submission of the final project report.

Resitting assessment

Resits will accord with the LSHTM's [Resits Policy](#)

Resources

Indicative reading list

Papers:

Coloma PM et al, Postmarketing Safety Surveillance, *Drug Saf*(2013) 36:183-197

Lindquist M, The need for definitions in Pharmacovigilance, *Drug Saf*(2007), 30: 825-830

Rothman KJ, Six persistent research misconceptions, *J Gen Intern Med* (2014) Jul;29(7):1060-4

Videos:

[How does the NHS in England work](#)

[Drug discovery and development process \(Australia\)](#)

[Drug Discovery and development process \(USA\)](#)

Other resources

A mixture of teaching modes will be used, including:

1. Electronic interactive materials provided through the School's online learning site, Moodle. Materials will include fully interactive self-directed sessions on each topic, audio/video lectures and case study vignettes, a compendium of key references (relevant papers and reports published in the last 5 years). These will be updated yearly to capture up-to-date knowledge and debates. The materials are self-explanatory and include guidance on their use. Students will also access other online materials, participate in module-specific discussion forums, real-time/recorded Collaborate tutorial sessions and access the LSHTM online library resources.
2. Interactive events with key experts on specific topics or to mark milestones in the teaching programme, online discussions and webinars.

The Module Organiser and tutors use Moodle as their primary means of communication with students and use it to make available a range of materials for studying the module. Students are also encouraged to participate in module-specific discussions on Moodle; make use of the online library facilities and will be required to submit assignments via an online assignment management system.

Students will be provided with all the material required for the project at the start of the module. They are not required to do any further literature searches or use additional material, but may supplement the material if they wish.



Teaching for Disabilities and Learning Differences

The module-specific site on Moodle provides students with access to the module learning materials and online reading list (containing both essential and recommended readings), and additional resources including supplementary exercises and optional lecture recordings (where appropriate). All materials posted up on Moodle areas, including computer-based sessions, have been made accessible where possible.

The LSHTM Moodle has been made accessible to the widest possible audience, using a VLE that allows for up to 300% zoom, permits navigation via keyboard and use of speech recognition software, and that allows listening through a screen reader.

For students with special needs, reasonable adjustments and support can be arranged – details and how to request support can be found on the University of London Worldwide [website](#).