Module Specification 2018-19 Pharmacoepidemiology and Pharmacovigilance (Certificate of Achievement)

General information	
Module name	**Postgraduate Professional Development course in Pharmacoepidemiology and Pharmacovigilance**
Title and name of final certification	Certificate of Achievement in Pharmacoepidemiology and Pharmacovigilance.
Module code	PCM100
Module Organiser(s)	Luigi Palla and Sarah-Jo Sinnott
Target audience	If you are working in the pharmaceutical industry or the drug regulatory authorities then this course may be of interest to you.
Level and credit value	Where credits are assigned to each module of a programme, the specified level of the Framework for Higher Education Qualifications in England, Wales and Northern Ireland (FHEQ) indicates the depth, complexity and intellectual demand of learning involved. The credit value indicates the amount of learning expected in terms of an estimated notional number of hours of learning needed, where one credit represents 10 notional hours of learning. The European Credit Transfer and Accumulation System (ECTS) is used across Europe for credit transfer between institutions of higher education. Two UK credits equate to one ECTS credit. • This module is at Level 7. • 30 UK credits (15 ECTS) are awarded on successful completion of this module.
Awarding body	University of London
Registering bodies	Registering bodies: University of London and London School of Hygiene & Tropical Medicine (LSHTM)
Academic direction	London School of Hygiene & Tropical Medicine
Accreditation	Not applicable
Language of study and assessment	English
Mode of study	Flexible and online study.
Blended learning	Not applicable.
Module structure	Four sections in total, including the Project (see module content below).
Maximum and minimum periods of registration	The minimum and maximum period of registration, from a student's effective date of registration, is one and two years respectively.
Duration	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.
Dates	Tutorial support for this distance learning module is available from the beginning of November through to the end of May.

Accreditation of Prior Learning (APL)	This module does not allow APL.
Keywords	Pharmacoepidemiology, pharmacovigilance, risks and benefits of drug use, adverse drug effects (ADEs), pharmaceutical risk management.
Entrance requirements and fees	
Entrance requirements	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. 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).
English language requirements	A strong command of the English language is necessary to benefit from studying the module. Applicants whose first language is not English or whose prior university studies have not been conducted wholly in English must fulfil LSHTM's English language requirements with an acceptable score in an approved test taken in the two years prior to entry.
Student selection	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. This module is also open to LSHTM research degree students.
Internet access	Students will require regular access to a computer (or mobile device*) with an internet connection to use the University of London website and the Student Portal to access the LSHTM's online learning site, where the programme study resources are located. The computer should have at least the following minimum specification: • a web browser (the latest version of Firefox, Chrome or Internet Explorer). This must accept cookies and have JavaScript enabled; • screen resolution of 1024 x 768 or greater; • sufficient bandwidth to download documents of at least 2-5 MB; and the following applications installed: • Microsoft Word and Excel software; • a pdf reader. * Full mobile access to online resources is not available for all programmes. **Additional requirements** • Students will need to use a calculator. • A headset/microphone will be required to participate in "real time" online discussions.
Students with specific access requirements	The University of London welcomes applications from disabled students and/or those who have specific access requirements. The University will make every effort to provide reasonable adjustments to enable those with specific access requirements to have the same opportunity as all other students to successfully complete their studies.

	Students with a disability or others who may need special arrangements to assist in taking examinations (such as separate room or special aids) should complete the relevant section of the application form, or contact the Inclusive Practice Manager. Requests will be considered by a University panel, whose purpose is to ensure that students with disabilities and/or specific access requirements are neither advantaged nor disadvantaged by such arrangements when compared with other students. For further information, see the Inclusive Practice Policy.
Fees	The fee for this short course will be £4,730 in 2018/19 payable in one instalment prior to the start of the course.
Funding and scholarships	No scholarships are offered for this course.
Educational aims, objectives and learning outcomes	
Overall aim	This module aims 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.
Intended learning outcomes	By the end of this module, students will: 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.

Content	
Module content	**Module content** The module includes the following topics: **Pharmacoepidemiology** Students will learn about the fundamentals of pharmacoepidemiology, its conduct, practical uses and limitations in determining the effects of medications in large groups of people. The statistical basis underpinning pharmacoepidemiology will also be introduced, and students will integrate statistics and epidemiology to gain competence in critically appraising pharmacoepidemiology studies. Individual sessions are as follows: • Introduction to Pharmacoepidemiology and Pharmacovigilance • Introduction to critical appraisal of trials • Essential Statistics for Epidemiology Part I - Descriptive Statistics • Essential Statistics for Epidemiology Part 2 - Inference • Design and Usefulness of Observational Studies • Measures of occurrence and measures of effect • Selection and information bias • Confounding and Interaction • Case only designs • Propensity scores • Critical Appraisal of Systematic Reviews & Meta-Analysis I • Critical Appraisal of Systematic Reviews & Meta-Analysis II • Correlation and linear regression • Logistic regression • Survival analysis • Critical Appraisal of Cohort Studies • Power and Sample Size • Critical Appraisal of Case-Control Studies • Introduction to comparative effectiveness research • Electronic Healthcare Records in Pharmacoepidemiology: Pragmatic Randomised Controlled Trials • Introduction to Pharmacoepidemiology and Applications in the Pharmaceutical Industry • Introduction to comparative effectiveness research. **Pharmacovigilance** Students will be introduced to the key elements of pharmacovigilance and its basis within drug regulation. 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. Principles will largely be demonstrated within the European legislative context, whilst recognizing these general principles apply more broadly throughout the world. Individual sessions are as follows: • Pharmacovigilance and Spontaneous ADR reporting systems: A Regulatory Perspective • Overview of Pharmaceutical Risk Management • Vaccine Risk Management • Medications in Pregnancy • Guidelines on Pharmacoepi, and Pharmacovigilance: Role of CIOMS, ICH, ISPE, ENCePP • Statistical Methods of Signal Detection within spontaneous reporting

	systems • Signal Prioritisation • Regulatory Pharmacovigilance – the EU perspective • Drug Safety Decision Making Using Evidence from a Range of Sources • Post-marketing benefit-risk assessment. **Health economics** Students will be introduced to the fundamental concepts involved in assessing the cost effectiveness of health technologies and methodologies used to assess the health related quality of life. Real world examples will be used to illustrate concepts. Individual sessions are as follows: • The role of pharmaceutical data in NICE's appraisal of new & current health technologies • Assessing the Health Related Quality of Life • Case Study: A Health Technology Appraisal. **Project** A project integrating the course thematic areas listed above will enable students to demonstrate their global understanding of pharmacoepidemiology and pharmacovigilance. A currently live drug safety issue will be selected, for which students will be given a selection of study reports (usually 5 or 6). The task is to critically appraise the evidence, to make decisions based on the totality of the evidence, and to make suggestions for future regulatory action and research. Broadly, the project contains the following sections: 1. A section to introduce the subject (which will differ from year to year). 2. A critical appraisal of each of the individual studies provided, including an assessment of their strengths and weaknesses 3. An overall assessment of the possible causal association presented in the papers. 4. A recommendation of any regulatory action students think is warranted based on the evidence provided.
Learning time	The notional learning time for the module totals 300 hours, consisting of: • **Directed self-study** (reading and working through the provided module material) **and self-directed learning** (general reading around the subject, library, Moodle discussion forums) ≈ 160 hours • **Assessment, review and revision** ≈ 40 hours • **Project** ≈ 100 hours, approximately divided as follows: <u>Self-directed learning</u> Background reading 4 hours Note-making/consolidation 32 hours Online (Moodle) discussions 4 hours <u>Assessment, review, revision</u> Preparation and writing of interim summary/Report: 50 hours Student-led academic adviser guidance and feedback: 10 hours

Teaching, Learning and Assessment	
Study resources provided or required	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 and learning methods	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 majority of work on the project will be by self-directed learning. 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.
Assessment details	This module will be assessed by 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. Learning objectives 1,2,3,4 and 6 are assessed by the project and objectives 1,2,3,4 and 5 are assessed by the unseen examination.

Assessment dates	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.
Student support and guidance	
University of London	The following summarises the support and guidance available to students: • University of London Student Guide: This provides information which is common to all students and gives information about matters of importance from the start of a student's relationship with the University of London through to their completion of their studies. • Programme Regulations • University of London library: Registered students may use the resources located within the Senate House library (for a small additional fee). • The Student Charter: This outlines key mutual obligations between the University of London and its students.
LSHTM	• The LSHTM online learning site (Moodle). This gives online access to the main course materials, discussion forums, information on assignments, links to essential and recommended readings (where relevant and available), past examination papers and examiner reports, and study skills' resources. • LSHTM online library resources. • Student support staff are available to offer help and advice on administrative matters. Communication may either be via the online 'Student Support Help' discussion forum on Moodle or by email, and sometimes by Skype if needed. • The module has one Module Organiser (MO) and a team of tutors assigned to it. The tutor team provides academic support in the following ways: o assisting in interpreting and understanding the material presented by answering queries on the online discussion forums o grading and providing written feedback on any assignments o offering some real-time 'webinars' in which students are encouraged to participate. • The tutors are specialists in their subject area. • The LSHTM Student Handbook, available on the LSHTM Moodle site, provides guidance on all aspects of the programme. It includes background information about the programme, advice on getting started,

	studying as a distance learner and organising study time, a description of the resources and programme materials available and how to access them, networking and support issues, procedures for assessment and examinations (including programme deadlines). • Students are encouraged to exchange ideas with other students on the course and to organize mutual support via email or other forms of communication. An online discussion forum 'Student Cafe' is available within the LSHTM Moodle site which is accessible to students only, while individual contact details can be made available through the Student Network Directory (subject to student consent). This contains contact details of other students on the course so students can build up their own network if they wish (for example, to organise study groups).
Quality evaluation and enhancement	
Parity of award standards	Every programme of study is developed and approved by an academic institution of the University of London, or a consortium with representation by more than one academic institution to the same standards and requirements as would be applied in the institution/s concerned. Learning materials are written and examinations are set and marked by academic staff who are required to apply the University's academic standards.
Review and evaluation mechanisms	Procedures are in place to assure the standards of the course and the quality of the student experience. Improvements are made as necessary to ensure that systems remain effective and rigorous. • Annual programme reports are produced for all programmes in order to review and enhance the provision and to plan ahead; • Every year independent external examiners submit reports to confirm that the programmes have been assessed properly and meet the appropriate academic standards; • VLEs provide students with the opportunity for informal feedback and discussion.
After course completion	
The Alumni Association	The London School of Hygiene and Tropical Medicine welcomes former students to its alumni association and this is free to join.
Contacts	
Contact email	The LSHTM distance learning courses and modules are run in collaboration with the University of London. Enquiries may be made via the Student Advice Centre.
Admission deadlines	Applications for LSHTM distance learning courses and modules are managed by the University of London. To apply to take this module, click the relevant link on the University of London website. Key deadlines are as follows: ➢ Application deadline: 30 September ➢ Registration deadline: 15 October ➢ Start date: 1 November
About this document	
This module specification applies for the academic year 2018-19 Last revised/approved 7 December 2017 by Luigi Palla/Sue Horrill	

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