



## MODULE SPECIFICATION

<b>Academic Year (student cohort covered by specification)</b>	2024-25
<b>Module Code</b>	2611
<b>Module Title</b>	Introduction to Pharmacovigilance
<b>Module Organiser(s)</b>	Christopher Rentsch
<b>Faculty</b>	Epidemiology and Public Health
<b>FHEQ Level</b>	Level 7
<b>Credit Value</b>	<b>CATS:</b> 15 <b>ECTS:</b> 7.5
<b>HECoS Code</b>	100246; 100260; 100270; 101049; 101317
<b>Mode of Delivery</b>	Online intensive module
<b>Mode of Study</b>	Online synchronous teaching during teaching week and directed self-study, through online materials via Moodle
<b>Language of Study</b>	English
<b>Pre-Requisites</b>	Students need to meet general MSc entry criteria.
<b>Accreditation by Professional Statutory and Regulatory Body</b>	Not currently accredited by any other body.
<b>Module Cap (Indicative number of students)</b>	Up to 40 participants will be accepted, inclusive of students taking the full Professional Certificate in Pharmacoepidemiology & Pharmacovigilance, and those taking this module individually.
<b>Target Audience</b>	Elective module for students on DL MSc Clinical Trials, PG Diploma Clinical Trials. Also open to any other student who meets pre-requisites for the module and who wishes to learn about pharmacovigilance.
<b>Module Description</b>	You will be introduced to the key elements of pharmacovigilance and its basis within drug regulation. Within the risk management elements of the course, you 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
<b>Duration</b>	1 week of 5 days



<b>Timetabling slot</b>	Typically, 1 <sup>st</sup> full week of February. Materials, including pre-recorded and live lectures and practicals, not released until this week.
<b>Last Revised (e.g. year changes approved)</b>	September 2024

## Module Aim and Intended Learning Outcomes

<b>Overall aim of the module</b>
The overall module aim is to: <ul style="list-style-type: none"> <li>- equip students with a thorough understanding of the concepts and practice of pharmacovigilance.</li> </ul>

<b>Module Intended Learning Outcomes</b>
Upon successful completion of the module a student will be able to: <ol style="list-style-type: none"> <li>1. Demonstrate an understanding of the legislation and regulations for pharmacovigilance and pharmacoepidemiology activities in the UK and internationally.</li> <li>2. Gain a thorough understanding and reflect critically upon the role of spontaneous reporting in pharmacovigilance.</li> <li>3. Critically apply understanding the key principles of Health Technology Appraisal.</li> <li>4. Apply pharmacoepidemiology evidence to decision making, risk management planning and responses to adverse drug events</li> </ol>

## Indicative Syllabus

<b>Session Content</b>
The module is expected to cover the following topics: <ul style="list-style-type: none"> <li>• Pre-course content and welcome</li> <li>• Introduction to Pharmacovigilance</li> <li>• Spontaneous Reporting</li> <li>• Risk Management Planning</li> <li>• Proactive Pharmacovigilance</li> <li>• Health Technology Assessment</li> <li>• Vaccine Pharmacovigilance</li> <li>• Safety Concerns in Pregnancy</li> <li>• Global Pharmacovigilance</li> <li>• Signal Detection</li> <li>• Risk-Benefit Management</li> </ul>



## Teaching and Learning

### Notional Learning Hours

Type of Learning Time	Number of Hours	Expressed as Percentage (%)
Contact time/self-directed learning	<b>30</b>	<b>20</b>
Assessment, review and revision	<b>120</b>	<b>80</b>
<b>Total</b>	<b>150</b>	<b>100</b>

### Teaching and Learning Strategy

The module will be taught online through pre-recorded and live lectures and live, interactive, small group practicals. Students are expected to learn through both directed and self-directed study. All live sessions are recorded and posted on the course Moodle page to allow students to review and revise content at their convenience. No materials can be made available until the week of the course.

## Assessment

### Assessment Strategy

During the module there are a number of formative Assessments such as interactive workshops and Exam practice questions. These Assessments aim to monitor the study progress of the students; therefore, they do not contribute to the final mark of the course.

There is one assessed component. The Exam will consist of multiple short answer questions (SAQs), covering the following 4 topics:

- Adverse drug reactions & risk/benefit
- Health economics
- Risk management and minimisation
- Spontaneous reporting, disproportionality

DL students taking this module are not eligible to be awarded the Professional Certificate in Pharmacoepidemiology and Pharmacovigilance (Cert P Epi & P Vig).



## Summative Assessment

Assessment Type	Assessment Length (i.e. Word Count, Length of presentation in minutes)	Weighting (%)	Intended Module Learning Outcomes Tested
Time limited assessment	The Exam comprises short answer questions covering all 4 topics listed above	100	All

### Resitting assessment

Resits will accord with [Chapter 8a](#) of the LSHTM Academic Manual.

A candidate who fails the Exam will be entitled to re-sit the Exam on one further occasion at the time the Exam is offered in the next academic year.

## Resources

Students should access to the course Moodle page for all materials related to the course.

## Teaching for Disabilities and Learning Differences

All lectures and live sessions are recorded and placed on the course Moodle page. Each lecture is recorded and uploaded with the accompanying set of slides. All papers suggested for reading are made available on the course Moodle page.