

5.00 credits

25.0 h + 5.0 h

Q2

Teacher(s)	Halleux Séverine ;Hamdani Jamila ;Hardt Karin ;Henrard Séverine (coordinator) ;
Language :	French
Place of the course	Bruxelles Woluwe
Learning outcomes	
Evaluation methods	Oral examination. The final mark is the arithmetic average of the marks for the clinical studies part, which is worth 10/20, and the pharmacovigilance and drug risks part, which is worth 10/20
Teaching methods	The course will be given in the form of lectures illustrated by concrete examples
Content	<p>At the end of the course, the student will be able to:</p> <ul style="list-style-type: none"> <li>- Understand the historical, scientific, statistical, legislative and ethical aspects of clinical studies in the context of drug development.</li> <li>- To know the different participants in a clinical study and the implementation of a clinical trial in a hospital pharmacy in particular.</li> <li>- Understand and analyse the safety of drugs in the context of an overall benefit/risk assessment.</li> <li>- Understand the basic principles of pharmacovigilance and its methods (adverse event reporting, signal detection, signal evaluation, decision making, communication) and describe the different possibilities of risk minimisation activities.</li> </ul>
Other infos	This course is intended for students who have a thorough knowledge of pharmacy (e.g. students who have a bachelor or master degree in pharmaceutical sciences).
Faculty or entity in charge	FARM

Programmes containing this learning unit (UE)				
Program title	Acronym	Credits	Prerequisite	Learning outcomes
Advanced Master in Hospital Pharmacy	HOPI2MC	5		