UCLouvain

# whopi2110

*2021*

# Etudes cliniques, pharmacovigilance et risques médicamenteux

| 4.00 credits | 25.0 h + 5.0 h | Q2 |
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| 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 | At the end of the course, the student will be able to:<br>- Understand the historical, scientific, statistical, legislative and ethical aspects of clinical studies in the context of drug development.<br>- To know the different participants in a clinical study and the implementation of a clinical trial in a hospital pharmacy in particular.<br>- Understand and analyse the safety of drugs in the context of an overall benefit/risk assessment.<br>- 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. |
| 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 | 4 | | |