Universidad de Navarra

Pharmacovigilance (MIDI)

Guía docente 2025-26

INTRODUCTION

Overview: Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It plays a crucial role in ensuring the safety and efficacy of medicines, thereby protecting public health.

Pharmacovigilance is governed by strict regulatory and legislative standards and guidelines, and subject to regular audit and inspection. Consequences of non-compliance would include, but are not limited to, financial penalties, imposed limitations on/withdrawal of marketing authorisations, and most importantly a potential risk to public health.

This course provides an overview of the principles of pharmacovigilance (PV), a key function in all pharmaceutical companies to ensure continuous oversight of benefit/risk of medicines and the early identification and management of safety concerns.

The aim is to understand the basic principles of PV and drug safety, including the basis of adverse drug reactions, management of PV activities, QPPV responsibilities and oversight, pharmacovigilance in post-marketing and clinical safety, benefit-risk management, and experiences from pharmacovigilance inspections among other topics.

Título: Pharmacovigilance

Type: Core Subject

ECTS: 1ECTS

Course and semester: first course, second semester

Language: english

Module II: Drug development

Course area: Preclinical and clinical development

Professor responsible: Josep Termens, Almirall

Schedule: VER CALENDARIO

- **Location**: Room 10 Science library building

LEARNING OUTCOMES (Competencies)

CB7: Students are able to apply the knowledge acquired and their problem-solving skills in new or unfamiliar environments within broader (or multidisciplinary) contexts related to their area of study.

CB8: Students are able to integrate knowledge and face the complexity of making judgements based on incomplete or limited information, including thoughts on the social and ethical responsibilities linked to the application of their knowledge and judgements.

CB9: Students know how to communicate their conclusions, knowledge and ultimate reasons that support them to specialised and non-specialised audiences in a clear and unambiguous way.

***CB10*:** Students possess the learning skills that will enable them to continue studying in a largely self-directed or autonomous manner.

***GC2*:** Work as part of multidisciplinary teams and collaborate with other professionals in the area.

GC3: Identify the shaping elements of today's society, recognise its diversity and multiculturalism, being able to work in an international context.

GC4: Identify and know how to create strategies and actions aimed at achieving the objectives set and specify the necessary resources to carry them out in the field of a pharmaceutical company.

GC5: Knowing the techniques and current trends related to research, development and innovation of medicines.

***GC6*:** Possess critical capacity to make the necessary decisions and adapt to new situations that may arise in the pharmaceutical companies and related fields.

CE10: **Evaluate pharmacovigilance strategies focused on the detection of new indications and the prevention of adverse effects of medicines.**

PROGRAM

Introduction and objectives

• Pharmacovigilance – Background

• PV legal framework

• ICSR/Safety Reports Management

• Periodic Safety Update Reports

• PV Agreements

• PV Quality system

• Audits and inspections

• Signal detection

• Risk Management Plans

EUQPPV rol/local QPPV roles

PV in digital media/the future of PV

PV in Clinical Development

Questions and Answers

EDUCATIONAL ACTIVITIES

1ECTS x 25h= 25h

Theoretical lectures: 6h (0,24 ECTS)

Practical cases: 2h (0,08 ECTS)

Individual work: 15h (0,6 ECTS)

Assessment: 2h (0,08 ECTS)

ASSESSMENT

ORDINARY EXAMINATION

The final grade will be based on the following:

- Attendance to all sessions: 10%

- Active participation in class: 10%

- First test (Day I): 20%

- Final test (Day II): 60%

RE-SIT EXAMINATION

Students who do not pass the Final exam (minimum score of 5 out of 10), must re-sit an exam with the same characteristics previously mentioned in the Final exam.

Special Needs

Students with special educational needs must contact the Faculty/School's Study Coordination Office in advance to obtain authorization for accommodations (for example, more time for exams). This authorization must be sent by the student to the professor. It is recommended that this be done at the beginning of the semester.

ATTENTION

Please note that any attempt at fraud, copying, plagiarism, or other irregular behavior constitutes a serious infraction, as defined in Title IV "Rules of Academic Discipline for Students" within the System of Rules on Coexistence at the University of Navarra (Rules on Coexistence UNAV).

OFFICE HOURS

Make an appoinment by email:

- Josep Termens: josep.termens@almirall.com

BIBLIOGRAPHY AND RESOURCES

Web pages AEMPs, EMA, FDA, ICH

OMS Pharmacovigilance information

Good Pharmacovigilance Practices (EU)