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INSTITUTO POLITÉCNICO
DE BRAGANÇA

Course Unit	Pharmacovigilance				Field of study	Pharmacy	
Bachelor in	Pharmacy				School	School of Health	
Academic Year	2022/2023	Year of study	3	Level	1-3	ECTS credits	5.0
Type	Semestral	Semester	2	Code	9549-644-3205-00-22		

Workload (hours)	135	Contact hours	T	-	TP	60	PL	-	TC	-	S	-	E	-	OT	7,5	O	-

T - Lectures; TP - Lectures and problem-solving; PL - Problem-solving, project or laboratory; TC - Fieldwork; S - Seminar; E - Placement; OT - Tutorial; O - Other

Name(s) of lecturer(s)	Xavier Taboada Costa

Learning outcomes and competences

At the end of the course unit the learner is expected to be able to:
1. To fit Pharmacovigilance as instrument of control in public health in a context of global intervention
2. To understand the managgement of the Pharmacovigilance in Portugal
3. To obtain the clinical general knowledge's of adverse reactions and evaluate when notify them
4. Acquire advanced methods of detection and reporting of adverse reactions
5. To evaluate and to interpret Pharmacovigilance outcomes
6. To stimulate the learners for the importance of an active intervention in Pharmacovigilance, as future professionals of health

Prerequisites

Not applicable

Course contents

Theoretical-Practical Lessons: 1. Pharmacovigilance as an instrument of drug security in health; 2. Conceptual and nanagement process in Pharmacovigilance; 3. Statistical Pharmacovigilance data interpretation; 4. Practical interpretation of clinical cases.

Course contents (extended version)

1. Overall Approach to Quality
   - General Notions about Quality (Concepts, Historical retrospective)
   - General boarding of quality in health
2. Pharmacovigilance as an instrument of guarantee of quality in health
   - Definition
   - Importance and aims
   - Historical notes about the practices in Pharmacovigilance
   - Legal and regulative fitting
   - The importance of Infarmed- National Institute of Pharmacy and Medicine.
3. Management of Pharmacovigilance in
   - Management of the portuguese Pharmacovigilance
   - European and International Guidelines of Pharmacovigilance
   - Monitoring of adverse reactions
   - Causal attribution rules of adverse reactions
4. Pharmacovigilance in clinical trials
   - Drug development stages
   - Stages of Clinical Trials
5. Security measures in pharmacovigilance
   - Report of information
   - Preventive measures taken by Infarmed
6. General clinical knowledge of adverse reactions
   - Classification by target-organ
   - medRA terminology
   - Factors that increase the possibility of adverse reactions
7. Methods of detection and reporting of adverse reactions
   - Clinical cases
   - Interpretation of therapeutic profiles
8. Interpretation of statistical results of Pharmacovigilance

Recommended reading

1. ANDREWS, Elizabeth B. ; MOORE, Nicholas (2014). Mann's pharmacovigilance. Wiley Blackwell.
2. Maria, A. V. (2003). Farmacovigilância em Portugal. Lisboa: Instituto Nacional da Farmácia e do Medicamento.
3. Waller, P. , & Harrison-Woolrych, M. (2017). An Introduction to Pharmacovogilance. Wiley Blackwell.
4. Doan, T. , Renz, C. , Lievano, F. , Bhattacharya, M. , & Scarazzini, L. (Eds.). (2018). Pharmacovigilance: A Practical Approach. Elsevier Health Sciences.
5. Mastroianni, P. , & Varallo, F. R. (2013). Farmacovigilância para Promoção do Uso Correcto de Medicamentos. Porto Alegre: Artmed.

Teaching and learning methods

Teaching and learning methods: Expositive method; Practical exemplification; Learner's participation and explanation of doubts; Group work involving Clinical Cases of Pharmacovigilance, and adverse reactions os medicines, interpretation of therapeutic profiles and write filling of simulated adverse reactions reporting forms.

Assessment methods

1. Alternative 1 - (Regular, Student Worker) (Final)
   - Intermediate Written Test - 70% (Individual Written Test Applies minimum score according pedagogical regulation.)
   - Development Topics - 30% (Research work/Investigation on adverse drug reactions)
2. Alternative 2 - (Regular, Student Worker) (Supplementary, Special)
   - Final Written Exam - 100% (Individual Written Test)
3. Alternativa 3 - (Student Worker) (Final)
   - Final Written Exam - 100% (Individual Written Test)

Language of instruction

1. Portuguese
2. Portuguese, with additional English support for foreign students.

Electronic validation

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