

Module title:	Planning and monitoring of clinical trials	ECTS	1
Polish translation:	Planowanie i monitorowanie testów klinicznych		
Course:	Veterinary Medicine		

Module language:	English	Stage:	JM-FVM
Form of studies: ☒ intramural ☐ extramural	Type of module: ☒ basic ☐ mandatory ☐ directional ☒ elective	Semester: 7	☒ winter semester ☐ summer semester
Academic year:		2022/2023	Catalogue number: FVM-V-JMSS-07W-ED04_23

Module coordinator:	dr Piotr Pietrzak		
Teachers responsible for the module:	dr Piotr Pietrzak		
Unit responsible for the module:			
Faculty in charge:	Faculty of Veterinary Medicine		
Objectives of the module:	Objective of the module is to acquaint students with methodology of clinical tests, their planning, required procedures and the role of veterinary surgeon in the monitoring of the clinical experiments on animals.		
Teaching forms, number of hours:	a) E-lectures; hours 15		
Teaching methods:	e-lectures, discussion Detailed schedule will be defined by the coordinator of the course at the beginning of semester. Detailed organization of consultations will be defined by the coordinator of the course at the beginning of semester.		
Formal prerequisites and initial requirements:	Animal physiology, Veterinary microbiology		
Learning outcomes:	Knowledge: Student knows how to plan clinical trial. Student knows self and researcher responsibilities and obligations in light of the animal protection law and occupational health and safety regulations.	Skills: Student appropriately interprets responsibility of the veterinary surgeon towards laboratory animals and experiments on animals. Student evaluates various stages of clinical trial performed on living animals.	Competences: Student can critically evaluate personal actions and actions of others in lieu of the animal protection law and occupational health and safety regulations.
Assessment methods:	Online test, 10 questions No extra assessment methods are anticipated. In case of unforeseen, unusual circumstances mandatory remote teaching and remote assessment methods might be adopted.		
Formal documentation of learning outcomes:	eHMS entry. Records collected in the course portfolio i.e. individual records of student results, presence lists, database of oral and written questions, written assessments of the students.		
Elements impelling final grade:	100% test results: 1-5 pts 2 (failed) 6 pts 3 (sufficient) 7 pts 3.5 (sufficient +) 8 pts 4 (good) 9 pts 4.5 (very good) 10 pts 5 (excellent)		
Teaching base:	University e-learning platform		
Mandatory and supportive materials : 1. A Practical Guide to Managing Clinical Trials. Joann Pfeiffer and Cris Wells, Taylor & Francis Ltd. 2020 2. A Concise Guide to Clinical Trials. Allan Hackshaw, John Wiley and Sons Ltd. 2019 3. Statistical Methods for Clinical Trials. Mark X. Norleans, Taylor & Francis Ltd. 2019 4. Drug Products for Clinical Trials. Donald Monkhouse et al. Taylor & Francis Ltd. 2019			
Relevant scientific publications including those of the module coordinator.			
ANNOTATIONS Maximum of 12 participants.			

Quantitative summary of the module:

Estimated number of work hours per student (contact and self-study) essential to achieve presumed learning outcomes of the module - base for quantifying ECTS:	30 h
Total ECTS points, accumulated by students during contact learning:	1 ECTS

Learning outcomes of the module relative to the learning outcomes of the subject:

Outcome category	Learning outcomes:	Learning outcomes relative to the course outcomes	Impact on the each of course outcomes
Knowledge -	Student knows how to plan clinical trial.	A.W.16, A.W.18, A.U.4, B.W.5	1
	Student knows self and researcher responsibilities and obligations in light of the animal protection law and occupational health and safety regulations.	A.W.22, B.W.6, C.W.2, C.W.3, C.W.4	1
Skills -	Student appropriately interprets responsibility of the veterinary surgeon towards laboratory animals and experiments on animals.	A.U.12, A.U.14, A.U.15, A.U.19, B.U.1	1
	Student evaluates various stages of clinical trial performed on living animals.	A.U.6, A.U.14, A.U.15, A.U.16, A.U.19, B.U.20	1
Competences -	Student can critically evaluate personal actions and actions of others in lieu of the animal protection law and occupational health and safety regulations.	A.U.16, B.W.7, C.W.2, K.S.1, K.S.5, K.S.6, K.S.11	2