SZKOŁA GŁÓWNA GOSPODARSTWA WIEJSKIEGO

Planning and monitoring of clinical tests

Educational subject description sheet

Basic information

Field of study Veterinary Medicine	**Didactic cycle** 2024/25
Speciality -	**Subject code** WETFVMS_D.540.01732.24
Organizational unit Faculty of Veterinary Medicine	**Lecture languages** english
Study level long-cycle	**Mandatory** Elective subjects
Study form full-time studies	**Block** Major subjects
Education profile General academic	**Disciplines** Veterinary medicine

Coordinator	Piotr Pietrzak
Teacher	Piotr Pietrzak

Period Semester 7	**Examination** Pass with grade **Activities and hours** Lecture: 15	**Number of ECTS points** 1

Goals

Code	Goal
C1	Objective of the module is to acquaint students with methodology of clinical tests, their planning, required procedures and the role of the researcher/investigator in the monitoring of the clinical experiments on animals and humans.

Entry requirements

None

Subject's learning outcomes

Code	Outcomes in terms of	Effects	Examination methods
Knowledge – Student knows and understands:			
W1	plan and monitor clinical trial, self and researcher responsibilities and obligations in light of the human and animal protection law and occupational health and safety regulations	A.W16, B.W5	Oral credit
Skills – Student can:			
U1	appropriately interpret responsibility of the researcher/investigator towards experiments on animals humans. evaluate various stages of clinical trial performed on living animals and humans.	A.U12, A.U14, A.U15, B.U1, B.U3	Oral credit
Social competences – Student is ready to:			
K1	critical evaluation of personal actions and actions of others in lieu of the animal humans protection law and occupational health and safety regulations.	KS.4, KS.8	Oral credit

Study content

No.	Course content	Subject's learning outcomes	Activities
1.	Clinical trail palning and monitoring. New methods of clinical trial monitoring and data collection.	W1	Lecture
2.	Knowledge of ICH and GCP requirements.	U1	Lecture
3.	Based on the knowledge student can critically evaluate the study documents and collected data.	K1	Lecture

Course advanced

Activities	Methods of conducting classes
Lecture	Lecture

Activities	Examination method	Percentage
Lecture	Oral credit	100%

Activities	Credit conditions
Lecture	1. Online test - 10 questions 2. In case of unforeseen, unusual circumstances mandatory remote teaching and remote assessment methods might be adopted.

Literature

Obligatory

1. 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

Optional

1. 1. Statistical Methods for Clinical Trials. Mark X. Norleans, Taylor & Francis Ltd. 2019 2. Drug Products for Clinical Trials. Donald Monkhouse et al. Taylor & Francis Ltd. 2019

Calculation of ECTS points

Activity form	**Activity hours***
Lecture	15
Preparation for the test	4
Self-study on the content covered in class	7
Preparation of a multimedia presentation	4
Student workload	**Hours** 30
Number of ECTS points	**ECTS** 1

* hour means 45 minutes

Effects

Code	Content
KS.4	Absolwent jest gotów do korzystania z obiektywnych źródeł informacji
KS.8	Absolwent jest gotów do pogłębiania wiedzy i doskonalenia umiejętności
A.U12	Absolwent potrafi komunikować się z klientami i z innymi lekarzami weterynarii
A.U14	Absolwent potrafi sporządzać przejrzyste opisy przypadków oraz prowadzić dokumentację, zgodnie z obowiązującymi w tym zakresie przepisami, w formie zrozumiałej dla właściciela zwierzęcia i czytelnej dla innych lekarzy weterynarii
A.U15	Absolwent potrafi pracować w zespole multidyscyplinarnym
A.W16	Absolwent zna i rozumie mechanizmy działania, losy w ustroju, działania niepożądane oraz wzajemne interakcje grup weterynaryjnych produktów leczniczych stosowanych u docelowych gatunków zwierząt
B.U1	Absolwent potrafi bezpiecznie i humanitarnie postępować ze zwierzętami oraz instruować innych w tym zakresie
B.U3	Absolwent potrafi przeprowadzać pełne badanie kliniczne zwierzęcia
B.W5	Absolwent zna i rozumie zasady przeprowadzania badania klinicznego i monitorowania stanu zdrowia zwierząt