



Subject card

Subject name and code	Preclinical and Clinical Examination of New Drugs, PG_00039063						
Field of study	Biotechnology						
Date of commencement of studies	February 2023	Academic year of realisation of subject			2022/2023		
Education level	second-cycle studies	Subject group			Optional subject group Subject group related to scientific research in the field of study		
Mode of study	Full-time studies	Mode of delivery			at the university		
Year of study	1	Language of instruction			Polish		
Semester of study	1	ECTS credits			1.0		
Learning profile	general academic profile	Assessment form			assessment		
Conducting unit	Department of Pharmaceutical Technology and Biochemistry -> Faculty of Chemistry						
Name and surname of lecturer (lecturers)	Subject supervisor	dr hab. inż. Iwona Gabriel					
	Teachers	dr hab. inż. Iwona Gabriel					
Lesson types and methods of instruction	Lesson type	Lecture	Tutorial	Laboratory	Project	Seminar	SUM
	Number of study hours	15.0	0.0	0.0	0.0	0.0	15
E-learning hours included: 0.0							
Learning activity and number of study hours	Learning activity	Participation in didactic classes included in study plan	Participation in consultation hours		Self-study	SUM	
	Number of study hours	15	1.0		9.0	25	
Subject objectives	Expanding knowledge on the topic of preclinical and clinical studies						
Learning outcomes	Course outcome		Subject outcome		Method of verification		
Subject contents	The stages of the formation of a new drug. Preclinical testing. Phases of clinical trials. Terms & Methodology. Ethics in biomedical research. Legal regulations: ICH GCP, Declaration of Helsinki, the Nuremberg Code. Roles and responsibilities in clinical trials. Informed Consent. The safety of drugs in clinical trial. Pharmacovigilance - pharmacological vigilance. Clinical trials that have brought progress in the treatment of people infected with HIV - examples. Clinical trials that have not been successful - examples. Clinical studies of biologically active compounds discovered by Polish scientists.						
Prerequisites and co-requisites							
Assessment methods and criteria	Subject passing criteria		Passing threshold		Percentage of the final grade		
	Test		60.0%		100.0%		
Recommended reading	Basic literature		„Badania kliniczne - organizacja, nadzór, monitorowanie”, pod redakcją Marcina Waltera, OINPHARMA, Warszawa 2004, wyd. 1 „Farmakodynamika. Podręcznik dla studentów farmacji” Janiec Waldemar, Krupińska Jolanta, PZWL, 2002				
	Supplementary literature		No				
	eResources addresses		Adresy na platformie eNauczanie:				
Example issues/ example questions/ tasks being completed	1. What are the differences between I and II Phase in Clinical Trials. 2. Describe the method of Fixed Doses in the determination of acute toxicity. 3. What is ICH GCP, enter basic assumptions.						
Work placement	Not applicable						