GDAŃSK UNIVERSITY OF TECHNOLOGY

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 2024	Academic year of realisation of subject	2023/2024
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