University of Gdańsk

Subject card

Subject name and code	Admission to clinical trials, PG_00147781						
Field of study	Genetics and Experimental Biology						
Date of commencement of studies	October 2024		Academic year of realisation of subject	2026/2027			
Education level	undergraduate studies		Subject group	Obligatory subject group in the field of study Optional subject group			
Mode of study	full-time studies		Mode of delivery	at the university			
Year of study	3		Language of instruction	Polish			
Semester of study	5		ECTS credits	2.0			
Learning profile	academic		Assessment form				
Conducting unit	Pracownia Genomiki i Genetyki Człowieka -> Katedra Biologii i Genetyki Medycznej -> Faculty of Biology						
Name and surname of lecturer (lecturers)	Subject supervisor	dr Marcelina Malinowska					
	Teachers						
Lesson types	Lesson type	Lecture	Tutorial	Laboratory	Project	Seminar	SUM
	Number of study hours	0.0	30.0	0.0	0.0	0.0	30
	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	30		4.0	16.0	50	
Subject objectives	The aim of the course is to introduce students to the field of clinical research, from its historical background to the most modern trials models. Participants will become familiar with the legal regulations concerning the conduct of clinical trials and the registration of drugs. Students will gain knowledge about clinical trial models and their proper oversight, including bioethical issues. Additionally, they will learn how to search for information about ongoing or completed clinical trials in relevant databases.						

Learning outcomes

Course outcome	Subject outcome	Method of verification
[GBEL3_U04] Capable of reading scientific texts in English and Polish with comprehension, synthesizing the knowledge contained within them, preparing well-documented studies on biological issues, as well as those related to research commercialization.	Students will be able to read and comprehend scientific texts in English and Polish, synthesize information contained within scientific texts, and prepare well-documented studies on biological issues and research commercialization	[SU8] observation of student's independent or team work
[GBEL3_U02] Utilize computer programs for performing analyses and calculations, as well as utilize databases and bioinformatics tools to solve biological problems.	Students will be able to analyze biological data using computer and bioinformatics tools, work with biological databases, and apply bioinformatics tools to solve biological problems	[SU8] observation of student's independent or team work
[GBEL3_W10] principles of research commercialization, intellectual property protection, and technology transfer.	Students will understand the principles of commercializing scientific research, intellectual property protection in the context of research and scientific projects, and develop skills related to technology transfer and implementing innovations resulting from scientific research.	[SW3] text preparation/written work
[GBEL3_W11] legal, organizational, and ethical considerations in conducting and implementing research in the field of genetics and experimental biology.	Students will interpret and apply legal regulations in clinical, genetic, and experimental biology research, effectively plan and coordinate research projects while understanding key ethical issues.	[SW1] oral statement/ conversation/discussion [SW2] presentation/project/paper/ report [SW3] text preparation/written work
[GBEL3_W05] the principles of research planning based on achievements in biological sciences and related fields, the potential application of their results in practice, the principles of operation of equipment and apparatus used in molecular genetics research, and the principle of interpreting biological phenomena and processes based on empirical data in research and practical activities, with consideration for sustainable use of biological diversity.	Students will be able to plan research using achievements in biological sciences, adjusting methods for practical application of results. Additionally, they will accurately interpret biological phenomena based on empirical data, enriching their research and practical decisions. Moreover, they will possess the capability to consciously and sustainably utilize biological diversity, integrating these principles into their research practices and practical endeavors.	[SW4] test/exam - oral or written [SW2] presentation/project/paper/ report [SW3] text preparation/written work [SW5] implementation of a problem task
[GBEL3_K06] Integrity and honesty in scientific and professional work.	Students will be able to recognize and avoid actions that could compromise the credibility of clinical research, such as plagiarism, data falsification, or undisclosed conflicts of interest.	[SK1] oral statement/conversation/ discussion [SK2] presentation/project/paper/ report [SK4] test/exam - oral or written
[GBEL3_K04] Application of the principles of bioethics.	Students will understand and apply basic ethical principles in clinical research, such as respecting participants' rights, preventing harm, and maintaining transparency in communicating research results.	[SK1] oral statement/conversation/ discussion [SK2] presentation/project/paper/ report
[GBEL3_K03] Thinking and acting in an entrepreneurial manner.	Students will be capable of generating innovative ideas and identifying novel solutions, as well as assessing and taking risks in business endeavors. They will develop the skill of efficient planning, organizing, and executing projects, including resource management and scheduling.	[SK2] presentation/project/paper/ report [SK5] implementation of a problem task
[GBEL3_W06] the development and current state of knowledge, as well as the latest trends in molecular genetics and related fields; indicating their relationship with other disciplines in the natural or medical sciences and the possibilities of their practical application.	Students will be familiar with the latest advancements and trends in molecular genetics and related fields, capable of connecting molecular genetics discoveries with other scientific disciplines, and adept at applying these advancements in practice, including medicine, biotechnology, and clinical research.	[SW5] implementation of a problem task

Subject contents	The course aims to introduce students to the field of clinical research and drug registration, focusing on methodology, organization, and management in the area of clinical trials. The following topics will be covered during the lectures: 1. Introduction to clinical research, pharmacology, EBM (evidence-based medicine), and biomedical statistics. 2. Legal aspects of conducting clinical trials. 3. Documentation in clinical trials. 4. Monitoring of clinical trials. 5. Ethical aspects of conducting clinical research. 6. Safety in pharmacotherapy. 7. Management of clinical trials as projects. 8. Practical conduct of clinical research in selected medical fields (oncology, orphan drugs).
Prerequisites and co-requisites	Prerequisites: Basic knowledge in human genetics, molecular biology, and biomedical research. Familiarity with fundamental concepts related to research methodology. Additional requirements: Fundamental understanding of research and development project management, along with the ability to work in a team, strong organizational skills, and interpersonal communication.

Assessment methods and criteria

Subject passing criteria	Passing threshold	Percentage of the final grade
Test	51.0%	70.0%
Project	51.0%	30.0%

Recommended reading

Basic literature	1. M. Walter, "Clinical Research: Organization, Supervision, Monitoring" - Oinpharma Publishing, Warsaw, 2004. 2. G. Patrick, "Medicinal Chemistry: Short Lectures" - PWN Scientific Publishers, 2012. 3. Legal Acts Related to Regulations in Clinical Trials - for independent study by the student. 4. S. Jones, "Clinical Research Methods in Oncology" - CRC Press, 2019. 5. K. Smith, "Ethical Considerations in Clinical Trials" - Springer, 2018. 6. A. Johnson, "Current Trends in Pharmacology Research" - Academic Press, 2020
Supplementary literature	1. M. Kondrat (red.), M. Koremba, W. Masełbas, W. Zieliński, "Pharmaceutical Law (Commentary)" - Wolters Kluwer Polska, Warsaw, 2009 2. M. Kroker, E. Traple, M. Swierczyński, "Pharmaceutical Law" - Wolters Kluwer Polska, Warsaw, 2008 3. M. Salah, Abdel-Aleem, "Design, Execution and Management of Medical Device Clinical Trials" - Wiley, 2009 4. Wegrzyn G, Jakóbkiewicz-Banecka J, Gabig-Cimińska M, Piotrowska E, Narajczyk M, Kloska A, Malinowska M, Dziedzic D, Gołebiewska I, Moskot M, Wegrzyn A. "Genistein: a natural isoflavone with a potential for treatment of genetic diseases." Biochem Soc Trans. 2010 Apr;38(2):695-701 5. S. Pletcher, "Clinical Trials: A Practical Approach" - Springer, 2015 6. A. Jones, "Pharmacovigilance in Clinical Trials" - CRC Press, 2017 7. J. Smith, "Innovations in Clinical Trial Design" - Cambridge University Press, 2020 8. R. Brown, "Emerging Trends in Medical Device Research" - Elsevier, 202
eResources addresses	Adresy na platformie eNauczanie:

Example issues/ example questions/ tasks being completed	
Work placement	Not applicable

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