INFORMATION ABOUT THE COURSE

Introduction to clinical trials

1. Basic information

Field of studies field of medical and health sciences, discipline: medical sciences **Unit responsible for the field of studies** Faculty of Medicine Bydgoszcz University of Science and Technology **Level of studies** Uniform master's studies **Profile of studies** General academic **Form of studies** Full-time	**Studies cycle** …….. **Course code** 17-EMS-ICT-SP1 **Language** English **Obligatory** Yes

Prerequisites	Knowledge of basic biological and medical concepts such as anatomy, physiology, pathology, and pharmacology, which is essential to understanding the context of clinical research. Method of assessment: Passing subjects designated as introductory is equivalent to meeting the prerequisites for the subject.
Introductory courses	Anatomy, Physiology with elements of clinical physiology, Pathophysiology, Pharmacology with toxicology
Coordinator	Karolina Matulewicz, PhD

Study period	**Form of assessment** **Form and hours of classes**	**ECTS credits**
Winter semester	Passing with a grade Lecture 30h	2.0

2. Learning outcomes

Code	**Description of learning outcomes**	**Learning outcomes reference**
Knowledge (student knows and understands):		
K1	The graduate knows and understands the basic quantitative parameters describing the efficiency of individual systems and organs, including the ranges of standards and demographic factors influencing the value of these parameters	B.W22.
K2	The graduate knows and understands the basic IT and biostatistical tools used in medicine	B.W23.
K3	The graduate knows and understands the principles of conducting scientific research for the development of medicine	B.W26.
K4	The graduate knows and understands the symptoms and course of diseases	O.W2.

K5	The graduate knows and understands the methods of diagnostic and therapeutic procedures appropriate for specific disease states	O.W3.
K6	The graduate knows and understands the ethical, social and legal conditions for practicing the medical profession and the principles of health promotion, and bases his knowledge on scientific evidence	O.W4.
K7	The graduate knows and understands the methods of conducting scientific research.	O.W5.

3. Programme contents

No.	Programme contents	Form of studies	Learning outcomes covered by the programme content
1	Clinical Trial Basics: • Introduction to clinical trials as a scientific method for assessing the efficacy and safety of medical therapies. • Discussion of the stages of clinical trials: from Phase I to Phase IV, including their objectives and procedures.	Lecture	K1, K2, K3, K4, K5, K6, K7
2	Ethical, social and legal aspects of clinical trials: • Ethical principles of conducting clinical trials: autonomy, patient welfare, justice. • Discussion of legal regulations concerning clinical trials, including requirements for patient consent and procedures for approval of trials by responsible institutions.	Lecture	K1, K2, K3, K4, K5, K6, K7
3	Evidence-Based Health Promotion: • A review of the latest scientific evidence on the effectiveness of various health promotion activities, e.g. educational campaigns, prevention programs.	Lecture	K1, K2, K3, K4, K5, K6, K7
4	Diagnostic Methods in Clinical Trials: • Discussion of various diagnostic methods used in clinical trials, including imaging (e.g., computed tomography, magnetic resonance imaging) and laboratory (e.g., blood and urine tests).	Lecture	K1, K2, K3, K4, K5, K6, K7
5	Therapeutic Methods in Clinical Trials: • A review of the different therapeutic methods used in clinical trials, including pharmacotherapy, gene therapy, cell therapy, and surgical interventions.	Lecture	K1, K2, K3, K4, K5, K6, K7
6	Basic quantitative parameters describing the efficiency of systems and organs: • A discussion of basic physiological and laboratory parameters used to assess the efficiency of individual systems (e.g. cardiovascular, respiratory, nervous) and demographic factors influencing these parameters.	Lecture	K1, K2, K3, K4, K5, K6, K7

7	Application of computer and biostatistical tools in medicine: • Training in basic computer and biostatistical tools used to analyze medical data, including statistical programs and databases.	Lecture	K1, K2, K3, K4, K5, K6, K7
8	Critical Appraisal of Research Findings: • Training in critical appraisal of research findings, including analysis of methodology, interpretation of data, and assessment of the strength of evidence.	Lecture	K1, K2, K3, K4, K5, K6, K7
9	Classification of research methodology: • Discussion of different types of research studies, such as experimental, observational, cohort, cross-sectional, randomized, placebo-controlled studies.	Lecture	K1, K2, K3, K4, K5, K6, K7
10	Planning and Execution of Research: • Training in planning and conducting research, including developing research protocols, selecting patients, collecting data, and quality control.	Lecture	K1, K2, K3, K4, K5, K6, K7
11	Scientific Communication and Clinical Trial Presentations: • Scientific communication in the context of clinical trials, including preparing presentations, writing scientific articles, and presenting research results at scientific conferences.	Lecture	K1, K2, K3, K4, K5, K6, K7
12	Forming Conclusions and Taking Responsibility for Decisions: • Forming conclusions based on the analysis of research results and taking responsibility for clinical decisions based on those conclusions.	Lecture	K1, K2, K3, K4, K5, K6, K7
13	Use of objective sources of information: • Use objective sources of medical information, such as peer-reviewed journals and medical databases.	Lecture	K1, K2, K3, K4, K5, K6, K7
14	Safety and professional responsibility: • Discussion of the principles of safe and responsible conduct within the scope of medical practice, including protection of patient data and adherence to ethical standards.	Lecture	K1, K2, K3, K4, K5, K6, K7

4. Methods of verifying and assessing the learning outcomes achieved by the student

Winter semester

Form of studies		
Lecture	**Methods of studies form:**	
	Lecture, Discussion	
	Methods of verification:	**Involvement:**

	Written test	100%
	Conditions for passing the course:	
	The condition for passing the course is to obtain a positive grade in the written test (single choice test). The test will cover the issues discussed during lectures. The test will include theoretical questions, practical tasks and case analysis, consistent with the topics covered in class.	

Learning outcomes	**Methods of verification**
	Written test
K1	X
K2	X
K3	X
K4	X
K5	X
K6	X
K7	x

5. Student workload – balance of hours and ECTS credits

Students activity		**Student workload Number of hours**
Classes conducted with the direct participation of an academic teacher or other persons conducting classes	Lecture	30
Student's own work	Preparing for classes	6
	Studying literature	6
	Preparing for a test	8
Total student workload		50
ECTS		2

One (teaching) hour is 45 minutes.

6. Literature

The list of required and recommended literature will be provided by the lecturer at the first meeting.