SYLLABUS

2017-2023

Academic year 2021/2022

1. BASIC INFORMATION CONCERNING THIS SUBJECT

Subject	**Clinical Trials; basic concepts, regulations and practical implementation**
Course code *	**Fak**
Faculty of (name of the leading direction)	**Medical College of Rzeszow University, University of Rzeszow**
Department Name	**Department of Experimental and Clinical Pharmacology**
Field of study	**Medical**
level of education	**Uniform Master studies**
Profile	**General academic**
Form of study	**Stationary / non-stationary**
Year and semester	**5th year, 9th semester**
Type of course	**Supplementary**
Language	**Polish/English**
Coordinator	**mgr farm. Piotr Bernat**
First and Last Name of the Teachers	**prof. dr hab.n.med. Piotr Tutka** **mgr farm. Piotr Bernat**

*** - According to the resolutions of the Educational Unit**

1.1. Forms of classes, number of hours and ECTS

Semester No.	Lecture	Classes	Conversation	Laboratory	Seminar	ZP	Practical	Other	**Number of points ECTS**
9					30				

1.2. The form of class activities

☐**classes are in the traditional form**

☐classes are implemented using methods and techniques of distance learning

1.3 Examination Forms

CREDIT WITHOUT GRADE (AN ESSAY ON A GIVEN TOPIC DISCUSSED DURING SEMINARS AND SINGLE CHOICE TEST

2.BASIC REQUIREMENTS

- Basic knowledge in the field of pharmacology

3.OBJECTIVES, OUTCOMES, AND PROGRAM CONTENT USED IN TEACHING METHODS

3.1 Objectives of this course

C1	Obtain an understanding of the clinical trials basics focused on GCP principles, applicable laws and regulations. Focus to grasp Polish and European regulations related to Clinical Trials
C2	Ability to identify a role of patients, investigators and other stakeholders engaged into clinical trials run at a clinical site.
C3	Gain ability to assume a role as a site team member during a course of clinical trials conduct.
C4	Ability to understand and explain different stages of the clinical trial: feasibility, selection process, site initiation visit, routine monitoring visits and closure. Capable to show principal behaviour during audits and inspections
C5	Ablility to understand an importance of scientific data and documents as main outputs of clinical trials.
C6	Obtain knowledge and skills on principal documents prepared for clinical trials; protocol, Investigator Brochure, pharmacy manuals, lab manuals and Investigational Medical Product Dossier
C7	Preparation of a clinical study with focus on study protocol: study title, objective, primary and secondary endpoints, eligibility criteria, study procedures, study design, table of study procedures, statistical considerations and other

3.2 OUTCOMES FOR THE COURSE

EK (the effect of education)	The content of learning outcomes defined for the class (module)	Reference to directional effects[1]
EK_01	Law regulations and principal methods applicable to medical experiments and other medical research inclusive basic methods of data analysis	**G.W8**
EK_02	Patients' rights	**D.W17.**
EK_03	Is able to explain a difference between prospective and retrospective trials, randomized clinical trials, case studies and experimental research as well classify them though reliable and quality index of scientific evidence	**B.U12.**
EK_04	Inform a patient about a goal, course and potential risk of proposed diagnostic or therapeutic activities as well obtain informed consent on those activities	**D.U6**
EK_05	Engage patients into a therapeutic process	**D.U7**
EK_06	Obey ethical principals in professional activities	**D.U13**
EK_07	Follow patient's rights	**D.U15**
EK_08	Maintain medical records of the patient	**E.U38**

[1]In the case of a path of education leading to obtaining teaching qualifications, also take into account the learning outcomes of the standards of education preparing for the teaching profession.

EK_09	Rules of scientific research conduct, observational and experimental studies as well in vitro facilitating development of medicine	**B.W29**
EK_10	Basics of evidence based medicine	**D.W23**
EK_11	Basic regulations of Pharmaceutical law (Poland)	**G.W10**
EK_13	Rules of team work	**D.W18**

3.3CONTENT CURRICULUM

Problems of classes

Course contents	**Hours**
1. Applicable law and regulations applicable to registration and conduct of clinical trials in Poland. Main entities engaged into clinical trials and GCP regulations with particular focus on E6 guide; Investigator, Ethics Committee, Regulatory Agency, Clinical Research Organization and Sponsor	3
2. Patients' rights and obligations in clinical trials, Informed Consent Process and essential elements proposed by GCP regulations, practical conduct how to obtain consent from patients along with maintenance of medical records. Roots of Helsinki Declaration	3
3. Responsibilities within a site team, 12 golden GCP rules essential for every site team member that takes part in a clinical trial. Focus on: eligibility verification and source data, audit trial concept, visit scheduling, investigational medical product allocations via interactive web-based response system, emergency unblinding and data entry to electronic Clinical Research Form	3
4. Roles and duties among CROs and Sponsors, audits and inspections. Preparation plan for an audit. Polish law related to inspection by Health Care Authority	3
5. Practical simulations: Feasibility and Pre-study visits. Preparation, handling and exception of feasibility questionnaire. Purpose of site selection visits.	3
6. Practical simulations: Initiation Visits, Routine Monitoring Visits and Closeouts. Finding a right patient, source records of patients participating in clinical trials, documentation of the visits as per study protocol.	3
7. Data Management: Source Data Verification, Source Data Review, Data Base Locks, Risk Based Monitoring. Lifecycle of data collected from patients	3
8. Protocols, Investigator Brochure and Investigational Medical Products Dossiers	3
9. Non-commercial Clinical Trials, including protocol design	3

3.4 Didactic methods

Classes: Problem introduction via presentation, presentations of experts invited for classes.

Group work (a case study, task solving, simulation, discussion, sub-group analysis with discussion).

4. METHODS AND EVALUATION CRITERIA

4.1 Methods of verification of learning outcomes

Symbol of effect	Methods of assessment of learning outcomes (Eg.: tests, oral exams, written exams, project reports, observations during classes)	Form of classes
EK_ 01-EK_13	Observations during classes , essay and final test	Sem.

4.2 Conditions for completing the course (evaluation criteria)

Seminars – knowledge assessment

Ongoing assessments during seminars including assessment of presentation skills, activity during the classes and ability to draw conclusion. Knowledge of applicable laws and regulations with particular focus on GCP regulations.. Students who are not present at classes without justification are not able to accomplish the course.

Scale:

5.0 – very active on classes, keen to study additional materials on top of those that are indicated in the framework.

4.5 – very active on classes, comprehensive knowledge of all materials indicated in literature

4.0 – active on classes, understands the subject at a decent level

3.5 – active on classes, shows knowledge gaps but understand basic of the filed

3.0 – not very active, avoid discussions related to the file, shows clear knowledge gaps

2.0 – not active on classes, look for other activities during the classes. Represents no knowledge in the filed of clinical trials

5. Total student workload required to achieve the desired result in hours and ECTS credits

Activity	**The average number of hours to complete the activity**
Contact hours (with the teacher) resulting from the study schedule of classes	30
Contact hours (with the teacher) participation in the consultations, exams	1
Non-contact hours - student's work (preparation for classes, exam, writing a paper, etc.)	4
SUM OF HOURS	35
TOTAL NUMBER OF ECTS	1

**It should be taken into account that 1 ECTS point corresponds to 25-30 hours of total student workload.*

6. TRAINING PRACTICES IN THE SUBJECT

NUMBER OF HOURS	To be determined

RULES AND FORMS OF APPRENTICESHIP	To be determined but coordinating teacher works on an internship for a few (up to 5) best students at a leading global CRO during the summer break.

7. LITERATURE

The obligatory books:

1. Declaration of Helsinki – Ethical principles for medical research involving human subjects
2. ICH Efficacy 6 (E6) Good Clinical Practice (GCP)
3. Clinical Trials (Badania Kliniczne); Teresa Brodniewicz, Marek Czarkowski, Katarzyna Domek-Łopacińska, Małgorzata Drop, Anna Dryja, Ewa Dynerowicz-Bal, Tomasz Dyszyński, Krystyna Forysiak, Grzegorz Grynkiewicz, Piotr Iwanowski, Grzegorz Jaworski, Antoni Jędrzejowski, Maria Kołtowska-Häggström, Tomasz Kosieradzki, Iwona Łagocka, Wojciech Masełbas, Marta Moskalik, Marcin Ossowski, Andrzej Ostrowicz, Izabela Pabisz-Zarębska, Maciej Siński, Adam Sobantka, Agata Sosnowska, Ewa Szkiłądź, Tomasz H. Zastawny, Waldemar Zieliński, Piotr Zięcik. ISBN 978-83-7556-894-3. 2016

Recommended literature:

- *FDA 21 CFR Part 11; Electronic Signatures*
- *FDA 21 CFR Part 50; Protection of Human Subjects*
- *FDA 21 CFR Part 54; Financial Disclosure by Clinical Investigators*
- *FDA 21 CFR Part 56; Institutional Review Boards (IRB)*
- *FDA 21 CFR Part 312; Investigational New Drug (IND) Application*
- *FDA Compliance Program Guidance Manual for Sponsor, CRO and Monitor Inspections*
- *EU Clinical Trials Directive 2001/20/EC and 2005/28/EC*
- *EU Clinical Trials Regulation 536/2014*
- *EU GCP Directive 2005/28/EC*
- *EU General Data Protection Regulation 2016/679*
- *UK Clinical Trials Regulations S.I. 2001/1031 and S.I. 2006/1928*

and academic papers/books indicated by teachers

Acceptance Unit Manager or authorized person