Study programme: Doctoral Academic Studies in Biomedical Sciences

Course title: PRINCIPALS OF GOOD CLINICAL PRACTICE

Teacher: Ivana M. Urošević, Biljana G. Drašković, Aleksandar L. Rašković, Olga J. Horvat, Zdenko S. Tomić, Isidora N. Samojlik, Sandra I. Stefan Mikić, Karmen M. Stankov, Gordana M. Velisavljev Filipović, Maja S. Ružić, Vesna M. Mijatović Jovin, Ivana A. Bajkin

Subject status: elective

Number of ESPB points: 15

Condition: -

Subject goal:

The aim of this course is to acquaint the PhD students with the basic principles of clinical trials, both academic and sponsored. After mastering the material, students should be able to read the study protocol in an informed manner, to analyze data on preclinical and existing clinical trials, to see their possible shortcomings and based on that to decide whether to participate in the clinical trial or not. They also need to know the ethical principles of clinical trials so that they can respect them. After mastering the course, students should be able to write an information sheet for the examinees, to extract a valid trial summary and to perform the examination in accordance with the principles of good clinical practice. Also, the ethics of certain clinical branches and their specificity will be discussed.

Subject outcome:

Knowledge: PhD students should be acquainted with the Helsinki Declaration and its modifications, with pre-clinical trials and their interpretation in order to understand and assess the safety of the early stages of clinical trials. They should be familiar with the basics of the clinical trial phases and their specifics. Also they should master the principles of good clinical practice related to the clinical trials management, working with study subjects and managing documentation and to respect the pharmaco-economic laws.

Skills: Developing the skill of communicating with patients within the trial. Developing plans and protocols for clinical research, as well as handling trials organization and implementation. Educating other research team members. Recognizing, monitoring and reporting different types of adverse events. Analyzing and processing obtained data. Monitoring the use of certain drugs in a controlled environment. Forming basic pharmaco-economic recommendations.

Subject contents

Theoretical lectures:

1. Basics of good clinical practice, introductory lecture
2. Clinical trial ethics, the Helsinki Declaration and its modifications
3. Basic phases of drug testing, introduction
4. Preclinical trials
5. Non-profit academic clinical trials and sponsored clinical trials - conflict of interest
6. Phase I clinical trials, bioequivalence
7. Phase II clinical trials
8. Phase III clinical trials
9. Phase IV clinical trials
10. Clinical trials, pharmaco-epidemiology
11. Basics of pharmacovigilance
12. Fundamentals of pharmaco-economics
13. Good clinical practice in pediatric patients; GCP fundamentals in surgery
14. Good clinical practice in geriatric patients
15. Ethical aspects of treating critically ill patients in the terminal phase of the disease

Practical lectures:

1. Preclinical data analysis
2. Clinical trials early stages analysis.
3. Clinical trial plan development
4. Basics of filling out test lists
5. Informed consent preparation
6. Conducting a pharmaco-epidemiological analysis
7. Conducting a pharmaco-economic analysis
8. Adverse events identification, analysis and reporting

Recommended literature:

Required

1. The declaration of Helsinki, 2005
2. Hutchinson DR. A practical guide to GCP for investigators, 1993
3. Vogenberg FR et al. Introduction to applied pharmacoeconomics, 2001.
4. Berger ML (ed). Health care, quality and outcomes, ISPOR book of terms, 2003.

Additional

1. WHO guidelines for GCP for trials on of pharmaceutical product, 1993
2. literature recommended by the lecturer.

Number of active classes	**Theory**: 60	**Practice**: 45

Methods of delivering lectures: Lectures, demonstration exercises, debates and discussions

Knowledge evaluation (maximum number of points 100)

practices: 30

oral exam: 70