1. Department: Pharmacology, Pharmacotherapy, and Clinical Pharmacology
2. Level of Training: Residency
3. Educational Program: 7R01142 “Clinical Pharmacology”
4. Year of Study: 1
5. Course Title: *Research Management*
6. Number of Credits: 4

7. Course Aim:

To study and substantiate modern approaches to the management of scientific research in clinical pharmacology aimed at improving the efficiency of planning, organizing, conducting, and analyzing clinical trials of medicinal products in accordance with current requirements of evidence-based medicine and international standards.

8. Course Objectives:

The course covers:

1. General and specific issues of clinical pharmacology, evidence-based medicine, and clinical trials related to the practical activities of a clinical pharmacologist and the use of medicinal products.
2. Principles of organizational and methodological work of a clinical pharmacologist in healthcare institutions related to the rational use and provision of medicines.
3. The formulary system in healthcare organizations within the framework of the Unified National Healthcare System.
4. Conducting rational pharmacotherapy based on the selection of drugs with proven clinical and economic effectiveness and safety, considering the patient’s pathological and physiological profile, and using international guidelines and clinical protocols.
5. Expert evaluation of pharmacotherapy and drug utilization, clinical and pharmacological assessment of medical therapy within the framework of clinical audit.
6. Identification, registration, and prevention of adverse drug reactions.
7. Conducting pharmacoepidemiological and pharmacoeconomic studies in healthcare organizations.
8. Providing consultative assistance to physicians and patients regarding the rational selection and use of medicines.

9. Course Content:

The discipline covers the principles and methods of effective management of scientific activities, including the organization, planning, financing, and evaluation of research projects. It focuses on developing skills for managing research teams, coordinating scientific efforts, optimizing the processes of knowledge and technology creation, utilizing AI and digital platforms, and implementing research results into practice.

10. Course Justification:

Modern research activities require specialists to possess not only deep professional knowledge but also the ability to organize, plan, and manage the research process. The course *“Research Management”* aims to form a set of research and managerial competencies that ensure the

effective implementation of scientific projects at all stages of their life cycle — from problem formulation and methodology design to data analysis and practical application of results.
The course is a key component in training residents as future researchers, fostering a systematic understanding of scientific organization and preparing them for independent and team-based research at a high professional level.

11. Learning Outcomes:

Mastering the course contributes to the development of the following scientific competencies:

1. Ability to formulate and substantiate a scientific problem, define goals, objectives, and research hypotheses.
2. Ability to design and conduct a research project, selecting appropriate methods and tools.
3. Skills in research project management, including stage planning, role distribution, and results monitoring.
4. Competence in data analysis and interpretation using modern digital technologies and statistical methods.
5. Ability for scientific communication, presentation of results, and participation in professional discussions.
6. Critical evaluation of professional literature in clinical pharmacology and conducting pharmacoepidemiological research in healthcare organizations.

RO5. Ability to formulate adequate research questions, collect, analyze, and process data using artificial intelligence tools and digital platforms for scientific research.
RO6. Ability to learn independently and teach other members of the professional team, actively participate in discussions, conferences, and other forms of continuous professional development in the field of clinical pharmacology.

Prerequisites:

Clinical Pharmacology (general issues of clinical pharmacology and clinical-pharmacological characteristics of specific drug groups and agents)

Postrequisites:

Drug Utilization Evaluation and Clinical-Pharmacological Expertise; Adverse Drug Reactions; Stages of Conducting Various Types of Clinical Trials; Personalized Pharmacotherapy (Therapeutic Drug Monitoring, Pharmacogenetics)

Recommended Literature

Main Sources:

1. *Practical Guide to Managing Clinical Trials* — JoAnn Pfeiffer & Cris Wells, 2020. A comprehensive guide to managing clinical trials, from site selection to study closure. BookGuyz + Taylor & Francis.
2. *Practical Guide to Clinical Data Management* (4th Edition) — Susanne Prokscha, 2024. Focuses on clinical data management according to current standards. Routledge.

3. *Advances in Pharmacokinetics and Pharmacodynamics* — edited by Panos Macheras, 2023. Covers modern topics in pharmacokinetics/pharmacodynamics relevant to clinical pharmacology research. SpringerLink.
4. *Recent Advances in Therapeutic Drug Monitoring and Clinical Toxicology* — edited by Seth Kwabena Amponsa