DISCIPLINE SHEET

1. Data about the programme

1.1.	"CAROL DAVILA" UNIVERSITY OF MEDICINE AND PHARMACY
1.2.	FACULTY OF MEDICINE
1.3.	DEPARTMENT - THE PRECLINICAL DEPARTMENT 1 – FUNCTIONAL SCIENCES
1.4.	DISCIPLINE - *CLINICAL PHARMACOLOGY*
1.5.	DOMAIN OF STUDY: HEALTH – Sectorally regulated within the European Union
1.6.	STUDY CYCLE: LICENCE
1.7.	STUDY PROGRAME: MEDICINE – ENGLISH MODULE

2. 2. Data about discipline

2.1.	Name of the discipline in the educational plan:				
2.2.	Discipline code: DD IV 11M				
2.3.	Discipline type (FD/SD/CD): SD				
2.4.	Discipline regimen (MD/OPD/): MD				
2.5.	The holder of the course activities Assoc. Prof. Aurelian Zugravu				
2.6.	The holder of the seminar activities : Assoc. Prof. Aurelian Zugravu Assoc. Prof. Smaranda Stoleru				
2.7. Year of study	IV	2.8. Semester	7 and 8	2.9. Type of evaluation (E/C)	E

3. Total estimated time (hours/semester of didactic activity an self preparation/study

I. Academic training (teaching, practical application, assessment)						
3.1. Nr hours/week	4	From which:	3.2. lecture	2 hours	3.3. seminary/ laboratory	2 hours
3.4. Total hours of educational plan	24 (6 weeks x 4 hours)	From which:	3.5. lecture	12 (6 weeks x 2 hours)	3.6. seminary/ laboratory	12 (6 weeks x 2 hours)
Evaluation (nr. of hours) : 7						
II. Self preparation/study						

Time allocation	hours
Study of course materials, textbooks, books, study of the recommended minimal bibliography	10 hours
Additional research in the library, research through the internet	4 hours
Performing specific activities for preparing projects, laboratories, elaborating reviews or other tasks	4 hours
Specific preparation activities for projects, laboratory work, assignments, and reports	4 hour
Tutoring	2 hours

Other activities		2 hours
3.7. Total individual study hours		26 hours
3.9. Total hours per semester (3.4.+ 3.7.)	50	
3.10. Number of credits	2	

4. Preconditions (where applicable)

4.1. of curriculum	
4.2. of competences	

5. Conditions (where applicable)

5.1. to conduct the lecture	PowerPoint presentations, use of multimedia systems, and projector
5.2. to conduct the seminar / laboratory	Equipped with the necessary apparatus for conducting practical activities

6. Learning outcomes

Knowledge	Skills	Responsibility and autonomy
- Knowledge of legislation and regulations in the field of medicine. - Knowledge of ethical principles in clinical drug research. - Knowledge of the development stages of a drug, from the idea to the marketing authorization and beyond. - Knowledge of the main models of clinical studies in the field of medicine. - Knowing how to evaluate the clinical effectiveness of a medicine. - Knowing how to evaluate the clinical safety of a medicine. - Knowing how to evaluate the clinical pharmacokinetics of a medicine.	- Acquiring the appropriate skills for interpreting the results obtained in clinical trials. - Acquiring the skills to notice the risk of deviation of results in clinical studies. - Acquiring the skills to assess the level of credibility of the results of a clinical trial. - Acquiring the skills to extrapolate the results of a clinical trial in therapeutics.	- Identification of the objectives to be achieved, the available resources, the conditions for their completion, work stages, working times, related completion deadlines and related risks - The ability to integrate in multidisciplinary teams with the identification of roles and responsibilities in a multidisciplinary team and the application of communication techniques and effective work within the team and in relation to the patient - The ability to make a presentation on a scientific topic and the effective use of information sources and communication resources and assisted professional training (Internet platforms, specialized software applications, databases, online courses, etc.) in a language of international circulation.

7. Course objectives (aligned with the learning outcomes)

7.1. General objective	Development, in the context of the Clinical Pharmacology discipline, of knowlege, abilities, attitudes and behaviors necessary for the optimal progress in the medical field

7.2. Specific objective	**Course objectives:** • The student's knowledge of the complex research process underlying the authorization of a drug (Marketing Authorization - APP) • Evaluation of the level of credibility of the results of a clinical trial. • Appreciation of the possibilities of extrapolation of the results of a clinical study in therapeutics. **Objectives of the seminars:** • Acquiring the skills to evaluate a clinical trial • Evaluation of the level of credibility of the results of a clinical trial. • Acquiring the skills to extrapolate the results of a clinical trial in therapy. • Acquiring the necessary skills to choose the optimal drug among all drugs with the same therapeutic indication for a specific patient, based on clinical trials.

8. Contents

8.1. Lecture	**Teaching methods**	**Observations**
Lecture 1 - Definition of clinical pharmacology - Regulations in the field of medicine - Clinical research ethics	Video projection. Discussions.	2 hours
Lecture 2 - Drug discovery. - Regulatory drug research - Marketing authorization - Post-authorization evolution	Video projection. Discussions.	2 hours
Lecture 3 - Clinical trial of the drug - Definition and generalities - Clinical trial models - Inclusion/non-inclusion/exclusion criteria	Video projection. Discussions.	2 hours
Lecture 4 - Parameters used in clinical trials - Clinical efficacy research (efficacy	Video projection. Discussions.	2 hours

parameters, safety parameters)		
Lecture 5 - Statistical processing - Bias factors.	Video projection. Discussions.	2 hours
Lecture 6 - Evaluation of clinical trials - Extrapolation of the results of clinical trials in therapeutics	Video projection. Discussions.	2 hours
Recent Bibliography - Fulga Ion: Bazele farmacologiei clinice, Ed. Medicală, Bucureşti, 2022 - Katzung Bertram: Basic and Clinical Pharmacology, 14th edition, Mc Graw Hill, 2021		

8.2. Laboratory/ practical lesson	**Teaching methods**	**Observations**
LP1 - Elements of legislation; pharmacovigilance elements	Video projection. Discussions. Examples.	2 hours
LP2 – SPC	Video projection. Discussions. Examples.	2 hours
LP3 - Formal evaluation of clinical trials	Video projection. Discussions. Examples.	2 hours
LP4 – Risk Analysis	Video projection. Discussions. Examples.	2 hours
LP5 – Avoiding influencing the results by bias factors	Video projection. Discussions. Examples.	2 hours
LP6 – Assessing the level of confidence in the results of a clinical trial and extrapolating the results to therapeutics.	Video projection. Discussions. Examples.	2 hours
Recent bibligraphy - Fulga Ion: Bazele farmacologiei clinice, Ed. Medicală, Bucureşti, 2022 - Katzung Bertram: Basic and Clinical Pharmacology, 14th edition, Mc Graw Hill, 2021		

9. Evaluation

Activity type	**9.1. Evaluation criteria**	**9.2. Evaluation methods**	**9.3. Percentage in the final grade**

9.4. Lecture	Acknowledging the theoretical aspects of the subject	Theoretical (written) exam – Multiple choice tests	70%
9.5. Seminary	Skills to critically analyze a drug's SPC applied in organ systems medication	Report evaluation	30%
9.5.1. Individual project (if applicable	-	-	-
9.6. Minimum performance standard			
• Use of medicines based on existing scientific evidence. • The final passing grade is grade 5. • The final mark is established based on the evaluation criteria taken into account in a weighted manner with the relationship: 70% for the written test and 30% for the report.			

Date of completion :

22.09.2025

Date of approval by the Department Council: