Course unit name: CLINICAL PHARMACOKINETICS OF ANTINEOPLASTIC DRUGS

1.- General information

Code	303008	Plan		ECTS	3
Type	Elective	Course	2026/2027	Periodicity	1st Semester
Department	Pharmaceutical Sciences				
Virtual Platform	Platform:	Studium:			
	URL de Acces:	https://studium.usal.es/			

Faculty: Pharmacy

Professor coodinator	Amparo Sánchez Navarro		
Department	Pharmaceutical Sciences		
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Center	Faculty of Pharmacy		
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Professor	Marina Holgado Madruga		
Department	Phisiology and Pharmacology		
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Professor	José Germán Sánchez Hernández
Department	Pharmacy Service at the University Hospital of Salamanca Pharmaceutical Sciences Department
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Center	Faculty of Pharmacy		
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2.- The course in the context of the Master´s Program

Treaning Module
Thirth block (out of five) of master program organization. See Academic Schedule

General aim of the subject
The objective of this subject is to review and apply the basic concepts of clinical pharmacokinetics (CPK) together with "*in silico*" and hospital tools for dosage optimization of drugs used for cancer diseases. Clinical PK contributes to the precision medicine in personalising drug dosages, according to patient characteristics. In addition, therapeutic drug monitoring (TDM) is addressed as a tool for dosage individualization to improve clinical outcomes in terms of efficacy and/or safety. Also physiologically based pharmacokinetic (PBPK) analysis is undertaken. All the above approaches are considered to implement model informed precision dosing (MIPD) in oncotherapy

Professional specialization
This topic is oriented to researchers and clinicians involved in clinical investigation, drug development and improvement of using antineoplastic drugs in clinical practice. These include Pyisicians, Pharmacists, Biotechnologists, Biologists, and other professionals integrated in multidisciplinary groups working on optimization of pharmacological treatment of cancer.

3.- Previous recommendations

A degree on life sciences topics.

4.- Aims of the subject

To provide theoretical and practical knowledge about antineoplastic drugs oriented to the study of its pharmacokinetics (PK) and the main factors responsible for PK variability.

To adquire the ability to apply modeling and simulation tools, as well as TDM practice, to consider PK variability for the selection of precision dosages in the clinical practice.

Specific aims:

- To know the mecanism of action of the main antineoplastic drugs used in the clinical practice
- To understand the population pharmacokinetic (PopPK) modeling and simulation methodology and the factors with a relevant impact on patient exposure to drugs (demographics, phisiopathological, genetics, etc.)
- To study the concepts and tools regarding TDM of antineoplastic drugs in the clinical routine
- To learn about phisiological based pharmacokinetic (PBPK) modeling and simulations approach and its application to *in silico* clinical trials
- To achieve a holistic knowledge on the operation in a hospital pharmacy service for development, validation and follow-up of oncological therapies

5.- Contents

TOPICS (LECTURES):

1. Mecanism of action of the main anticancer drugs used in clinical practice
2. Clinical pharmacokinetics: basic concepts and application to antineoplastic drugs
3. Population pharmacokinetics (PopPK)
4. Physiological Based Pharmacokinetic (PBPK) analysis
5. Model-informed precision dosing and follow-up criteria in oncologyc treatments

SEMINARS and HANDS-ON:

1. Data handling and Bayesian estimation
2. Implementation of population pharmacokinetic models
3. Parameters estimation of antineoplastic drugs: case reports
4. Aplication of PBPK models to oncology patients
5. *In silico* clinical trials
6. Development and validation of the oncology therapy in a hospital pharmacy service

6.- Skills to be acquired

Basic skills
Understanding the usefulness of clinical PK to evaluate factors with a significant impact on the response to pharmacological treatments
Application of PK tools for dosage individualization in the oncological patient
Ability to use the PopPK models to improve the efficacy and safety of treatments with antineoplastic drugs
Application of PBPK models for “first-in-human” dose estimation and dosage individualization in oncologic patients
Pharmacy validation and follow-up of oncological therapies in a University Hospital

Specific skills
- Interpretation and aplicacion of TDM results to optimize and individualize pharmacological treatments with antineoplastic drugs

- Using pharmacokinetic information to select the dosage regimen with the optimal benefit/risk ratio for antineoplastic drugs
- Ability to use software for performing clinical trials in virtual populations
- Undestanding the application of PBPK models for dosage optimization
- Understanding the multidisciplinarity of the clinical team involved in the validation and follow-up of onco-hematolologic therapies

7.- Teaching methodology

- Indroductory activity
- Lectures
- Seminars
- Hands-on
- Case reports discussions
- Focused activities: presentation, analysis and proposals related to scientific papers

8.- Estimated learning time

		Hours tutored by the teacher		Individual work (hours)	TOTAL HOURS
		Attendance required (hours)	Distance learning (hours)		
Lectures		11	8	10	29
Practices	- In classroom				
	- In laboratory				
	- In computer classroom	6			6
	- Countryside				
	- Visualization classroom				
Seminars		4		2	6
Work presentations and debates		7		8	15
Tutorials		2		2	4
Online activities					
Work preparation			5	7	12
Other activities		3			3
TOTAL		**33**	**13**	**29**	**75**

9.- Materials

Books

Individualizing Dosage Regimens of Antineoplastic Agents. In Individualized Drug Therapy for Patients: Basic foundations, Relevant software and clinical applications. Ed. Jelliffe R and Neely M. Elsevier. 281-306, 2017.

A First Course in Pharmacokinetics and Biopharmaceutics by David Bourne: **http://www.boomer.org/c/p4/**

Scientific Journals

- Therapeutic Drug Monitoring

- Clinical Pharmacokinetics
- British Journal of Clinical Pharmacology

Recommended lecture

- Veal GJ, et al. (2019) Pharmacodynamic Therapeutic Drug Monitoring for Cancer: Challenges, Advances, and Future Opportunities. Ther Drug Monit;41:142–159.
- Guidi M, eta al (2020). Parametric Approaches in Population Pharmacokinetics. J Clin Pharmacol. Oct 26. doi: 10.1002/jcph.1633. Epub ahead of print. PMID: 33103774. https://doi.org/10.1002/jcph.1633
- Darwich, A. S. et al. (2021). Model-Informed Precision Dosing: Background, Requirements, Validation, Implementation, and Forward Trajectory of Individualizing Drug Therapy. Annual Review of Pharmacology and Toxicology, 61(1), 225–245. https://doi.org/10.1146/annurev-pharmtox-033020-113257
- Mueller-Schoell A. et al. (2021)Therapeutic drug monitoring of oral targeted antineoplastic drugs. European Journal of Clinical Pharmacology 77:441–464. https://doi.org/10.1007/s00228-020-03014-8
- Guenka Petrova, Stiliyana Blagova, Konstantin Tachkov, Marlene Santos, James Bluett, Merita Rumano, Elena Kkolou, Elena Drakalska, Marija Arev, Mehtap Cakmak Barsbay, Denis Mulleman (2025). Therapeutic drug monitoring education: The current state. https://doi.org/10.1002/bcp.70252

10.- Assessment

Assessments on the performance of the student
Continous follow-up of the knowledge, skills ans abilities adquired by the students.
Student participation will be highly appreciated and positively taking into account.
Attendence and active participation in lectures and seminars (hands-on).
Comments and proposals to the case-studies
Scientific accuracy of the commentaries and answers to the questions amd debates during lectures and seminars
Presentation and debate of a scientific paper

Recommendations
Active participation in the proposed activities
Debate about the multidisciplinarity of the optimization of oncological treatments.