# ECVPT Pharmacokinetics Workshop: Basic concepts for future professionals (foundation module/refresher course)

### **Course Information**

#### **Key Areas**

- Pharmacokinetics and physiological understanding of PK parameters
- Clinical pharmacology
- Introduction to computational approaches for evaluation of PK parameters

#### About this course

The present course is organized for professionals involved in pharmacokinetic studies, clinical research or regulatory affairs but without specific skill in data analysis and interpretation. This course is also a valuable refresher course for professionals actively working in PK.

The aim of this course is:

- 1. To show non-kineticists that pharmacokinetics (PK) can be a useful tool to document drug efficacy and safety and more generally to understand the role of PK on drug discovery, drug development, drug submission and clinical pharmacology.
- 2. To understand the meaning and utility of the main PK parameters (<u>plasma</u> <u>clearance</u>, <u>volumes of distribution</u>, <u>plasma terminal half-life</u> and <u>bioavailability</u>).
- 3. Brief training session on how to use a PK software program (Phoenix WinNonlin).

The 3.5 day course will comprise a series of lectures and practical exercises, which delegates will solve utilizing to Microsoft Excel and the computer software Phoenix WinNonlin (version 8.4). Prior to the Workshop (a few weeks in advance), you will be provided with educational licences to download onto your personal PC, which you will bring to the Workshop (NB: not MAC compatible). All test exercises have been carefully designed to allow attendees to proceed in a step-by-step progressive manner. Tutor support will be available and correction of the exercise will be provided.

To achieve its objectives, the course is deliberately presented without (advanced) mathematical consideration but attendees are assumed to know what a logarithm and an exponential are and to have a basic knowledge of statistics.

We recommend this course for residents of the European College of Veterinary Pharmacology and Toxicology and also residents of other colleges where PK is an important part of the exam curriculum (for example anaesthesia). This course provides a brief introduction to the Phoenix WinNonlin interface (but not to population PK).

Course programme below

**Dates** From Tuesday 25th (afternoon) to Friday 28th March 2025

Time		Durat.	Activity	Activity description	Academic staff
13:00	13:30	00:30	Introduction	Meet and Greet - Overview of the course	
13:30	14:30	01:00	Lecture 1	Rationale for the effective use of	VARIOUS
				pharmacokinetics and pharmacodynamics in	LECTURERS (PLT)
				drug development	
14:30	15:00	00:30	Lecture 2	What needs to be validated for an analytical	VARIOUS
				technique; Statistical methods to test Linearity,	LECTURERS (LP)
				accuracy, precision, agreement of an analytical	
				technique	
15:00	15:30	00:30	Afternoon break, coffee		
15:30	17:30	02:00	Exercise 1	Building and validation of a calibration curve	VARIOUS TUTORS
			(start)	with Phoenix/WinNonlin; Notion of residuals,	(LP)
				weighting factors as proposed by Phoenix/WNL but	
				also 1/X and 1/X^2 using a user vector, back	
				calculations, including with an equation having a	
				quadratic components etc.	
17:30	18:30	01:00	End of the day. Pizza in the refectory		
18:30	19:30	01:00	Exercise 1	Building and validation of a calibration curve	VARIOUS TUTORS
			(continuation)	with Phoenix/WinNonlin;	LP (G60 after
					18h30)

## DAY 1 Tuesday, 25th March 2025 Room G60

## DAY 2 Wednesday, 26th March 2025, Conference Rooms 1+2

Time			Activity	Activity description	Academic staff
08:30	09:00	00:30	Lecture 3	Body clearance: underlying concepts	VARIOUS
					LECTURERS (PLT)
09:00	10:00	01:00	Lecture 3	Body clearance: an overview	VARIOUS
					LECTURERS (PLT)
10:00	10:30	00:30	Morning break, coffee		
10:30	11:30	01:00	Lecture 4	The half-life: an overview	VARIOUS
					LECTURERS (LP)
11:30	12:30	01:00	Lecture 5	Volume of distribution: an overview	VARIOUS
					LECTURERS (PLT)
12:30	14:00	01:30	Lunch		
14:00	15:30	01:30	Exercise 2	Phoenix WinNonlin: one compartment model , IV	VARIOUS TUTORS
			(start)	dosing and oral dosing	
15:30	16:00	00:30	Afternoon break, coffee		
16:00	18:00	02:00	Exercise 2	Phoenix WinNonlin: one compartment model , IV	VARIOUS TUTORS
			(continuation)	dosing and oral dosing	
Evening			Dinner at the Tandori Raj, Brookmans park		

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Time			Activity	Activity description	Academic staff
09:00	10:00	01:00	Lecture 6	Bioavailability (rate and extent): protocols	VARIOUS LECTURERS
				(plasma, urine, metabolites), estimation,	(LP)
				interpretation	
10:00	10:30	00:30	Morning break, coffee		
10:30	11:30	01:00	Lecture 7	Non compartmental analysis	VARIOUS LECTURERS
					(ABM)
11:30	13:00	01:30	Exercise 3	A test exercise to illustrate NCA with	VARIOUS TUTORS
			(start)	physiological interpretation	
13:00	14:30	01:30		Lunch	
14:30	16:00	01:30	Exercise 3	A test exercise to illustrate NCA with	VARIOUS TUTORS
			(continuation)	physiological interpretation (continued)	
Evening				Free evening, a chance to visit London by Night	

#### DAY 3 Thursday, 27th March 2025, Conference Rooms 1+2

## DAY 4 Friday, 28th March 2025, Conference Rooms 1+2

Time			Activity	Activity description	Academic staff
08:30	09:30	01:00	Lecture 8	Plasma protein binding: an overview	VARIOUS LECTURERS (PLT)
09:30	10:00	00:30	Exercise 4 (start)	<b>Estimation of Bmax, Kd</b> and NS using linear and Non Linear regression: <b>application to clinical situations</b>	VARIOUS TUTORS
10:00	10:30	00:30			
10:30	12:00	01:30	Exercise 4 (continuation)	Estimation of Bmax, Kd and NS using linear and Non Linear regression: application to clinical situations	VARIOUS TUTORS
12:00	12:30	00:30	Feedback	End of the workshop / debriefing / evaluations	LP PLT
12:30	13:00	00:30		Farewell	LP PLT