



5th EUROPEAN COURSE ON PHARMACOKINETICS AND PHARMACODYNAMICS OF PROTEIN THERAPEUTICS

PRINCIPLES AND PHARMACOMETRIC APPROACHES & INTRODUCTION TO SIMULATIONS WITH E-CAMPSIS

BARCELONA, SPAIN, 24-27 SEPTEMBER 2024

COURSE DIRECTORS

Bernd Meibohm, University of Tennessee, and Johan Gabrielsson, MedDoor AB, Gothenburg

ORGANIZERS AND REGISTRATION SUPPORT

Calvagone SAS, France

LOCAL HOSTS

Andreas Lindauer (Calvagone)

This 4-day course will introduce participants to basic principles in the pharmacokinetics and pharmacodynamics of novel therapeutic proteins and provide opportunities for basic hands-on exercises in the PK/PD evaluation of these compounds. Topics include target-mediated drug disposition, tissue and tumor penetration, first-in-human dose selection, immunogenicity, clinical pharmacology challenges, biosimilars, ADCs, bispecific antibodies and drug-drug interactions.

The course is a shortened version of the week-long course on 'Pharmacokinetics and Pharmacodynamics of Protein Therapeutics - Concepts and Hands-On Modeling and Simulation' that Profs Meibohm and Gabrielsson have offered for the last thirteen years in the United States.

On the 4th day, Calvagone will give a hands-on introduction to e-Campsis, the free online PK/PD simulator, with examples focused on protein PK.

Further information on e-Campsis can be found at www.e-campsis.com

COURSE LOGISTICS

COURSE VENUE

Hotel Icària, Av. d'Icària, 195, 08005 Barcelona

REGISTRATION FEE

Regular: **€2200** Academia/Trainee: **€800**

Early-bird registration (before June 30th 2024): 10% discount

Registration fee includes access to all course sessions, course material in electronic form, two months free access to e-Campsis pro, lunch and coffee breaks, and a joint dinner. Reservations will only be acknowledged and participation in the course guaranteed after receipt of both the registration form AND the registration fee. The number of course participants will be limited to 30. The number of slots for academic participants and trainees will also be limited.

PAYMENT INFORMATION

- An invoice will be sent upon reception of the registration form.
- Payment can be made preferably by electronic transfer, or alternatively by credit card via PayPal



ACCOMODATION

Rooms in the venue hotel can be booked here (<https://www.hotelicariabarcelona.com/>). No arrangements have been made with Hotel Icaria.

Alternatively, participants are free to enjoy the wide offer of hotels in Barcelona at walking distance or easily accessible by local transportation through the usual booking sites. Participants need to make their own hotel arrangements.

TRAVEL INFORMATION

Barcelona is easily accessible by plane from most European cities followed by a 30 min taxi ride to the venue.

Alternatively, going by the Airport-Shuttlebus may take about 1 hour.

CANCELLATION POLICY

If cancelled more than 30 days before the course starts, enrolled participants will be subject to a €750 (€275) registration fee for Industry (Academic). There will be no refund of fees if registration is canceled 30 days or less before the course begins. Substitution of enrolled course participants with another person from the same organization is acceptable.

CONTACT DETAILS OF THE ORGANIZER

Email registration@calvagone.com

Web <http://www.calvagone.com>

Time	Day 1 (09/24/2024)	Day 2 (09/25/2024)	Day 3 (09/26/2024)	Day 4 (09/27/2024)
Topic	Basic Concepts	PK/PD	Developmental Aspects	Simulations with e-Campsis
09:00	Introduction (Bernd & Johan)	Recap and Outline of the Day (Bernd & Johan)	Recap and Outline of the Day (Bernd & Johan)	Outline of the Day
09:15	Basic Pharmacokinetics of Proteins (Bernd)	TMDD: Steady-state relationship of ligand, target and complex I (Johan)	Clinical Pharmacology Challenges for Protein Therapeutics (Bernd)	Introduction to the Campsis simulation suite
09:45	<i>Discussion</i>	<i>Discussion</i>	<i>Discussion</i>	
10:00	Drug Disposition of Monoclonal Antibodies (Bernd)	TMDD: Steady-state relationship of ligand, target and complex II (Johan)	Disease States & Covariates Modulating PKPD of Proteins (Bernd)	
10:30	<i>Discussion</i>	<i>Discussion</i>	<i>Discussion</i>	Hands-on: Simulating a simple PK model in e-Campsis
10:45	Break			
11:00	Basic Concepts of Target-Mediated Drug Disposition I (Johan)	Tissue Distribution and Tumor Penetration	PKPD and Clinical Pharmacology of Bispecific Antibody Derivatives (Bernd)	Hands-on: Simulating different scenarios, post-processing of results
11:30	<i>Discussion</i>	<i>Discussion</i>	<i>Discussion</i>	Hands-on: Solve exercises of day 1-2 with e-Campsis
11:45	Basic Concepts of Target-Mediated Drug Disposition II (Johan)	Challenges in the Development of Antibody-Drug Conjugates (Bernd)	New expressions of effect-duration, importance of free analytes (Johan)	
12:15	<i>Discussion</i>	<i>Discussion</i>	<i>Discussion</i>	
12:30	Extravascular Administration of Proteins (Bernd)	First-In-Human Dose Predictions (Bernd)	Evaluation of Drug-Drug Interactions of Therapeutic Proteins (Bernd)	
12:50	<i>Discussion</i>	<i>Discussion</i>	<i>Discussion</i>	
13:00	Lunch			
14:00	Presentation of feasibility exercise (Johan & Bernd)	Presentation of Practical Biologics Exercise (Johan & Bernd)	Immunogenicity: Impact on PK and PD (Bernd)	Hands-on: First-in-human dose prediction with a minimal PBPK-TMDD model
14:30	Hands-on exercise	Hands-on exercise	<i>Discussion</i>	
15:15	Break			
15:30	Discussion of feasibility exercise (Johan & Bernd)	Discussion of Practical Biologics Exercise (Johan & Bernd)	Pattern Recognition in PK and PD (Johan & Bernd)	Hands-on: Sensitivity analysis and other advanced features
16:00-16:15	Wrap-up (Johan & Bernd)	Wrap-up (Johan & Bernd)	Wrap-up (Johan & Bernd)	Wrap up and farewell

The schedule may be subject to minor changes.





REGISTRATION FORM

5th European Course on Pharmacokinetics and Pharmacodynamics of Protein Therapeutics Principles,
Pharmacometric Approaches & Simulations with e-Campsis
September 24-27, 2024 Barcelona (Spain)

First name : Last name:

Degree: Title:

Organization: Business Address:

City: ZIP:

Country: Business Phone:

Email address:.....

Dietary Restrictions :
 Vegetarian Other:

REGISTRATION FEE FOR COURSE SESSIONS, COURSE MATERIAL, 2 MONTHS FREE ACCESS TO E-CAMPSIS PRO, LUNCH & COFFEE BREAKS (CHECK APPROPRIATE):

Deadline for early-bird registration: June 30th 2024

- | | |
|--|---|
| <input type="checkbox"/> Early-bird Industry | 1,980 EURO (+€25 by Credit Card) |
| <input type="checkbox"/> Early-bird Academic / Student <i>documentation of status required</i> | 720 EURO (+€10 by Credit Card) |
| <input type="checkbox"/> Industry | 2,200 EURO (+€25 by Credit Card) |
| <input type="checkbox"/> Academic / Student <i>documentation of status required</i> | 800 EURO (+€10 by Credit Card) |

PAYMENT BY (CHECK APPROPRIATE):

- Electronic transfer
- VISA / Master Card / PayPal

Please fill out and mail this form to registration@calvagone.com. An invoice will be sent to you with payment details. If you claim for academic registration (limited spots), mail a copy of your 2024 academic ID.

Reservations will only be acknowledged and participation in the course guaranteed after receipt of both the registration form AND the registration fee.

If cancelled more than 30 days before the course starts, enrolled participants will be subject to an €750 (€275) registration fee for Industry (Academic). There will be no refund of fees if registration is cancelled 30 days or less before the course begins. Substitution of another person from the same organization is acceptable.

RETURN SCANNED FORM, PAYMENT AND COPY OF ACADEMIC AFFILIATION TO:

Emilie Hénin Email: registration@calvagone.com
Information at: Web: <http://www.e-campsis.com>

ACCOMMODATION: The course is organized at Hotel Icaria. Accommodation is **NOT** included in the registration fee and needs to be organized by the participants themselves.

