



#### Target Audience

The workshop is intended for 20–35 clinical microbiologists or scientists from academia (or companies) who work or want to work in the field of pharmacokinetics and pharmacodynamics and increase their knowledge and understanding in this area. Participants should have a basic understanding of statistics and ideally have some experience with PK/PD.

#### Faculty Members

- Saiden Abbas, Nijmegen, NL
- Roger Brüggemann, Nijmegen, NL
- William Hope, Manchester, UK
- Pavol Jancura, Nijmegen, NL
- Klaus Skovbo Jensen, Copenhagen, DK
- Eleftheria Mavridou, Nijmegen, NL
- Joseph Meletiadis, Athens, GR
- Johan W. Mouton, Nijmegen, NL
- Anouk E. Muller, Rotterdam, NL
- Ursula Theuretzbacher, Vienna, AT

## Contact

#### Administrative Secretariat

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National and Kapodistrian  
UNIVERSITY OF ATHENS



ESCMID Postgraduate  
Technical Workshop

## A Statistical Approach to PK/PD Analysis in Practice

Athens, Greece  
8 – 11 October 2012

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Technical Workshop

## A Statistical Approach to PK/PD Analysis in Practice

#### Organisers

- ESCMID PK/PD of Anti-Infectives Study Group (EPASG)
- National and Kapodistrian University of Athens
- Radboud University Medical Centre of Nijmegen

#### Course Coordinators

- Eleftheria Mavridou, Nijmegen, NL
- Joseph Meletiadis, Athens, GR
- Johan W. Mouton, Nijmegen, NL

#### Course Objectives

- Provide guidance on how to implement adequate statistical analysis to evaluate the pharmacokinetic and pharmacodynamic data
- Understand PK/PD indices, principles of CART analysis and how to apply these to establish clinical breakpoints
- Learn how to perform univariate and multivariate analysis, linear and nonlinear regression analysis, including the ins and outs of the Emax model
- To clarify the principles of pharmacokinetic parameters (peak and trough levels, volume of distribution, area under the concentration curve) and the factors that affect them
- Explain how to perform compartmental and non-compartmental pharmacokinetic analysis
- Understand how to measure and analyse drug combination effects and how to determine synergy and antagonism, including the Greco and Bliss models
- Perform analysis with different software programs



# Course Programme

## Monday, 8 October 2012: Statistical analysis

- 13.00 Registration
- 13.15 Lunch
- 13.45 Welcome and Introduction. Joseph Meletiadis
- 14.00 Introduction to statistics. Pavol Jancura
- 15.00 Linear and nonlinear regression models. Pavol Jancura
- 16.00 Coffee break
- 16.15 Hands-on exercises
- 18.15 Interactive discussion. Concluding remarks of the first day
- 20.00 Welcome reception and dinner

## Tuesday, 9 October 2012: PK/PD analysis

- 09.00 Pharmacokinetic analysis. Roger Brüggemann
- 10.00 Pharmacodynamic analysis. Joseph Meletiadis
- 11.00 Coffee break
- 11.15 Hands-on exercises
- 13.00 Lunch
- 14.15 PK/PD analysis in animals. Eleftheria Mavridou
- 15.15 PK/PD analysis. Bridging animal with human data. William Hope
- 16.15 Coffee break
- 16:30 Hands-on exercises. PK/PD analysis. Curve fitting. Training with computer expert programs
- 18.30 Interactive discussion. Concluding remarks of the second day

## Wednesday, 10 October 2012: *in vitro-in vivo* correlation

- 09.00 Simulating *in vivo* conditions in *in vitro* PK/PD models. Joseph Meletiadis
- 10.00 Analysis and simulations of *in vitro and vivo* time kill curves. Johan W. Mouton
- 11.00 Coffee break
- 11.15 Population pharmacokinetics. Roger Brüggemann
- 12.15 Monte Carlo Simulations. Anouk E. Muller
- 13:15 Lunch
- 14.15 Determination of clinical breakpoints, CART analysis. William Hope
- 15.15 Power calculations for PK/PD studies. Klaus Skovbo Jensen
- 16.15 Coffee break
- 16:30 Hands-on exercises. Curve fitting and simulation Training with computer expert programs
- 18.30 Interactive discussion. Concluding remarks of the third day

## Thursday, 11 October 2012:

### Literature review: dissecting the top 10 papers

- 09.00 Pharmacokinetics. Roger Brüggemann
- 10.00 PK/PD modelling. Johan W. Mouton
- 11.00 Coffee break
- 11.15 Animal models for PK/PD studies. Eleftheria Mavridou
- 12.15 Bridging PK/PD with humans. Ursula Theuretzbacher
- 13.15 Concluding remarks of the last day, closure of the workshop.

# Organisation

## Course Venue

Titania Hotel Athens  
Panepistimiou 52  
Athens 106 78  
Greece  
www.titania.gr

## Registration Procedure

The registration form can be found on the ESCMID website at [www.escmid.org/education](http://www.escmid.org/education). Please return it to the course administrative secretariat by 29 July 2012.

## Registration Fee

EUR 850 for ESCMID members  
EUR 1000 for all others  
Industry participants (max 5 if fully booked)  
EUR 1250

The fee includes accommodation for three nights, breakfast, lunch, materials, but not travel cost. All attendants are required to supply their own Notebooks. If necessary, laptops can be provided for EUR 50 per day.

## Attendance Grants

ESCMID provides a number of attendance grants for ESCMID “young scientist members”. The grant covers the registration fee, but not travel or accommodation costs. Please apply via the ESCMID website at [www.escmid.org/education](http://www.escmid.org/education) before 29 July 2012. Applicants will be informed about their acceptance by 17 August 2012.