

The thirteenth advanced level workshop on

Pharmacokinetic - Pharmacodynamic data analysis:
A hands-on residential course using Phoenix WinNonlin v.6



ROYAL
PHARMACEUTICAL
SOCIETY

Sunday 15 - Thursday 19 May 2011
Moller Centre, Cambridge

In partnership with the
Swedish Academy of Pharmaceutical Sciences



www.rpharms.com/events

OBJECTIVES

OBJECTIVES

An advanced and well-established four-day residential course designed to:

- Provide an interface between the computer analysis of PK and PD data and physiological concepts.
- Equip delegates, through lecture sessions, with an advanced understanding of all aspects of the subject, including pharmacodynamic theory, interpretation of computer output, practical experimental design, discrimination between rival models and combining data of different sources.
- Give delegates the unique opportunity of access to the WinNonlin modeling package to undertake hands-on exercises on real-life case studies - allowing delegates to apply the concepts learnt in- lecture sessions to an extensive number of real-life problems and data-sets. Users of software other than WinNonlin will also benefit from the methods discussed in the lectures and hands-on sessions.
- Allow delegates one-to-one time with the expert course tutors in problem-solving sessions.
- Participants are encouraged to bring their own kinetic/dynamic data.
- Provide reference material for use after the course through a full resource pack and textbook relevant to predictive science.
- Allow delegates to network with course tutors and other delegates from the field through a full social programme.

Terms and Conditions

Should you find that you are not able to attend the event after booking a place, please advise us in writing as soon as possible. If a colleague is able to attend in your place and you notify us in writing, we are pleased to accept the substitution at no charge. In the event that it is necessary to cancel a registration, please notify us in writing. A processing fee is payable. For cancellations, the following refunds will apply: Over 30 working days before the event: 50% of the fee; 30 or less than 30 working days: nil. The time of notification is taken at the date of receipt of fax or letter. Substitution is permitted at any time if notified in writing. We reserve the right to amend the programme. In the unlikely event of cancellation of the event, delegates will receive a full refund of fees but we cannot be held liable for other expense incurred by delegates.



WHO SHOULD ATTEND

- Advanced level research scientists in the pharmaceutical industry, academia, regulatory agencies and contract research firms who have a minimum of 3-5 years of experience in PK/PD analysis and modelling.
- Participants who attended the earlier introductory workshop.
- Researchers with a working knowledge of WinNonlin who want to learn more about the advanced features of the programme.
- Primary and safety pharmacologists engaged in PKPD studies

WHAT PREVIOUS DELEGATES HAVE SAID

“I would like to thank the teachers for their patient, encouraging and often painstaking focus on our comprehension”

“The lecturers were really helpful and were ready for any type of question”

“This is certainly the best course that I have attended for several years”

LEARN FROM A TEAM OF EXPERTS



Dr Johan Gabrielsson is a Senior Principal Scientist at AstraZeneca R&D Mölndal. He is author of the book ‘Pharmacokinetic and Pharmacodynamic Data Analysis: Concepts and Applications’ 4th ed. (2006). He is academically affiliated with the Department of Pharmacology, Gothenburg University, Sweden. He has conducted numerous workshops on biological (PK/PD) data analysis within and outside the pharmaceutical industry.



Dr Daniel Weiner is a Senior Vice President and CTO at Pharsight Corporation. He is co-author of the book ‘Pharmacokinetic and Pharmacodynamic Data Analysis: Concepts and Applications’ 4th ed. (2006). He has conducted numerous workshops on biological (PK/PD) data analysis and has served as an expert consultant to the FDA.



VENUE

The Moller Centre in Cambridge is a modern and comfortable purpose-built conference and training venue in the grounds of Churchill College - easily accessible by road, train and air. Car park facilities are available.





PROGRAMME

Sunday 15 May

17.00 Registration
18.30 Welcome drinks reception
19.15 Course dinner

Tu
08

Monday 16 May

08:15 **Introduction**

08:30 **Pharmacodynamics (Equilibrium)**

Review of steady-state models 09
Steady-state models
Kinetics of drug action 10
Initial parameter estimates
Design issues and case studies

09:45 Coffee/tea 12

10:00 **Pharmacodynamics (Distributional delays)** 13

Steady-state models vs. time delay
Basic concepts on distributional delays
Modelling QT-data with link models
Design issues and case studies 15

10:45 **Hands-on session 1** 15

Inst. equil. models, steady-state, log-linear, sigmoidal
Incomplete datasets

12:15 Lunch 17

13:15 – 16:45 **Hands-on session 2** 18

Modeling EEG-data with link models
Modeling QT- & MAPD data with link models
Design issues and case studies 19

14:45 Coffee/tea

16:45 **Numerical grammar**

18:15 Course dinner

19:15 **Evening exercise on your own**





Tuesday 17 May

08:30

Pharmacodynamics (Turnover A)

Residual questions from day 1
Turnover concepts I - 'The gang of four'
Constant and variable baseline
Comparing link- and turnover models
Initial estimates
Design issues and case studies

09:45

Coffee/tea

10:00

Hands-on session 3

Turnover models I-IV
Turnover model I of blood clotting data

12:15

Lunch

13:15

Hands-on 3 cont.

Collapsing hysteresis loops
Design issues and case studies

15:00

Coffee/tea

15:15

Group exercise – FTIM compound selection

Compound evaluations
Dose prediction, dose nomogram
Assessment of safety margin

17:15

Wrap-up & project exercise

18:15

Course dinner

19:15

Optional Phoenix NLME demonstration

PROGRAMME



PROGRAMME



Wednesday 18 May

08:30

Pharmacodynamics (Turnover B)

Residual questions from Day 2
The thought process
Peak shifts
Limited production and loss
Synergy by means of turnover models
Transduction models
Irreversible response
Initial parameter estimates

Th
08

09

09:45

Coffee/tea

10:00

Hands-on session 4

Turnover models I-IV
Comparing IRP and Link
Design issues and case studies

10

12:15

Lunch

12

13:15

Hands-on session 4 cont.

Turnover models I-IV cont.
Fitting multiple dose PD data

13

15:15

Coffee/tea

14

15:30

Introduction and group exercises

Group Exercise I
Group Exercise II
Group Exercise III

15

15

17:15

Wrap-up & group exercise

Ph

18:45

Course dinner

Ph

Ph

20.00

Social programme

IM

De

wi





PROGRAMME

Thursday 19 May

08:30

Pharmacodynamics (Adaptation)

Residual questions from Day 3
Models for adaptation
Tolerance and rebound
Feed-back systems
Oscillating baselines
Initial parameter estimates

09:45 – 12.15

Hands-on session 5

Turnover models I-IV continue
Synergy
Transduction models
Irreversible response
Design issues and case studies

10:15

Coffee/tea

12:15

Lunch

13:15

Hands-on session 5 cont.

Feedback
Analyzing pd data from phase i study

14:15

Experimental design

Own datasets
Synergy

15:15

Summary

15:30

Close of course

Please note: all delegates will require a copy of the 4th edition of “Pharmacokinetic/ Pharmacodynamic Data Analysis: Concepts and Applications” (Swedish Pharmaceutical Press 2006, 1250 pages).

IMPORTANT INFORMATION

Delegates **MUST** bring their own laptops to the course. Instructions on downloading WinNonlin will be provided in advance of the course.





PKPD DATA ANALYSIS – 15-19 MAY 2011 REGISTRATION FORM

Delegates will be registered upon receipt of the completed form and will liable to pay the fees. Payment must be made before the start of the course. Fees inclusive of 4 nights' accommodation, meals and refreshments, a welcome reception, social programme, and a resource pack with full course documentation.

MEMBERS OF RPS OR SWEDISH ACADEMY	£2,415	<input type="checkbox"/>
NON-MEMBER	£2,565	<input type="checkbox"/>
MEMBER (NO ACCOMMODATION OR EVENING MEAL)	£1,995	<input type="checkbox"/>
NON MEMBER (NO ACCOMMODATION OR EVENING MEAL)	£2,150	<input type="checkbox"/>
COMPLIMENTARY TEXTBOOK (BEFORE 11/02/11)		<input type="checkbox"/>

Title	Forename	Surname
Job Title		Post code
Company		Email
Address		Telephone
Membership No.		

The contact details you have provided may be used to keep you informed about future RPSGB events, products and services. If you do not wish to receive such information by any of the methods listed below please indicate by ticking the corresponding box:

Mail ☐ Email ☐ Phone ☐ All ☐

Dietary Requirements	How did you hear about this event?
----------------------	------------------------------------

METHOD OF PAYMENT

☐ Debit/Credit Card
Someone will contact you to obtain card details.

☐ Bank transfer (Sort Code 60 60 04 Account Number: 70378193. National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB) Quoting ref: **MMS EVT 401**

ONE FORM PER PERSON PLEASE – PHOTOCOPIED FORMS ARE ACCEPTED
Please return this form to: Events Coordinator, Royal Pharmaceutical Society,
1 Lambeth High Street, London SE1 7JN

Fax: 020 7572 2506 Email: events@rpharms.com
Tel: 020 7572 2640 Web: www.rpharms.com/events

NB. IF YOU DO NOT RECEIVE A CONFIRMATION OF YOUR PLACE VIA EMAIL WITHIN 5 WORKING DAYS OF SUBMITTING YOUR REGISTRATION FORM PLEASE LET US KNOW

