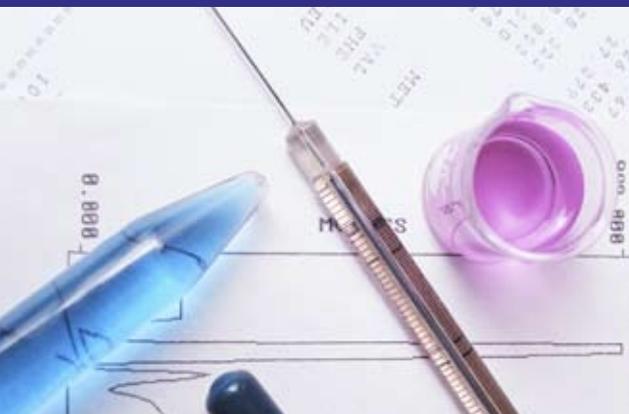


The Eleventh Advanced Level Workshop on

Pharmacokinetic - Pharmacodynamic Data Analysis:

A hands-on residential course using WinNonlin



Royal
Pharmaceutical
Society
of Great Britain

Sunday 17 - Thursday 21 May 2009 at
Maddingly Hall, Cambridge, UK

In partnership with the
Swedish Academy of Pharmaceutical Sciences



www.rpsgb.org/events

OBJECTIVES

An advanced and well-established 4 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-

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.

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”

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 relevant reference documents.
- Allow delegates to network with course tutors and other delegates from the field through a full social programme.

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 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 FDA.

VENUE



Madingley Hall is an old country house set in the charming village of Madingly, situated approximately three miles from the university city of Cambridge. Madingly is easily accessible by rail, road and air. Free car parking facilities are available

PROGRAMME

Sunday 17 May

- 17.00 Registration
18.30 Welcome drinks reception
19.15 Course dinner

Monday 18 May

08:15 **Introduction**

08:30 **Pharmacodynamic (Equilibrium)**

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

09:30 Coffee/tea

09:45 **Pharmacodynamic (Distributional delays)**

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

10:30 **Hands-on session 1**

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

12:00 Lunch

13:00 – 16:30 **Hands-on session 2**

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

14:30 Coffee/tea

16:30 **Numerical Grammar**

18:00 Course dinner

19:00 **Evening exercise on your own**

Tuesday 19 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
- 09:30 Coffee/tea
- 09:45 **Hands-on session 3**
Turnover models I-IV
Turnover model I of blood clotting data
- 12:00 Lunch
- 13:00 **Hands-on 3 cont.**
Collapsing hysteresis loops
Design issues and case studies
- 14:45 Coffee/tea
- 15:00 **Group exercise – FTIM compound selection**
Compound evaluations
Dose prediction, dose nomogram
Assessment of safety margin
- 17:00 **Wrap-up & project exercise**
- 18:00 Course dinner
- 19:00 **QTc lecture**

PROGRAMME

Wednesday 20 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
- 09:30 Coffee/tea
- 09:45 **Hands-on session 4**
Turnover models I-IV
Comparing IRP and Link
Design issues and case studies
- 12:00 Lunch
- 13:00 **Hands-on session 4 cont.**
Turnover models I-IV cont.
Fitting multiple dose PD data
- 15:00 Coffee/tea
- 15:15 **Introduction and Group exercises**
Group Exercise I
Group Exercise II
Group Exercise III
- 17:00 **Wrap-up & Group exercise**
- 18:30 Course dinner
- 19.45 Social programme

Thursday 21 May

08:30

Pharmacodynamics (Adaptation)

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

09:30 – 12.00

Hands-on session 5

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

10:00

Coffee/tea

12:00

Lunch

13:00

Hands-on session 5 cont.

Feedback
Analyzing pd data from phase i study

14:00

Experimental design

Own datasets
Synergy

15:00

Summary

15.15

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). A complimentary copy of this textbook will be given to delegates who register before Monday 16 February 2009. Delegates registering after this date must order and pay for a copy of the book in advance of the course.

IMPORTANT INFORMATION

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

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

RPSGB or Swedish Academy members: £2,345 **Non-members: £2,495**

Registering before 16 February 2009 and claiming a complimentary textbook

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

By giving us your details you are agreeing to be added to our electronic and postal mailing list and receive information on our events. Please note that your information will not be sold and will be handled in accordance with the Data Protection Act and the Society's Privacy Policy. Tick here if you do not wish to be added to the mailing list.

Dietary Requirements	How did you hear about this event?
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METHOD OF PAYMENT

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

Debit/Credit card Maestro Mastercard Visa Amex

Card No.	Security No.	Issue No.
Card holder's name and address (if different from above)	Expiry	
	Signed	

ONE FORM PER PERSON PLEASE – PHOTOCOPIED FORMS ARE ACCEPTED
Please return this form with your payment to: Science Programme Admin Assistant,
Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN
Fax: 020 7572 2506 Email: events@rpsgb.org (Tel: 020 7572 2640)

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

CANCELLATION AND REFUND

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 14 days: 90% of the fee; less than 14 but over 3 working days: 50% of the fee; three or less 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. The RPSGB reserves the right to change the programme or cancel the event if necessary. RPSGB does not accept liability for any expenses incurred by delegates.