



The Tenth Advanced Level Workshop on Pharmacokinetic - Pharmacodynamic Data Analysis: A Hands-on Course Using WinNonlin



A 4-day residential course organised by the
Royal Pharmaceutical Society of Great Britain and the
Swedish Academy of Pharmaceutical Sciences

Sunday 18 - Thursday 22 May 2008
at Maddingley Hall, Cambridge, UK

www.rpsgb.org/worldofpharmacy/events



Royal
Pharmaceutical
Society
of Great Britain







This advanced workshop provides an interface between the computer analysis of PK and PD data and physiological concepts. Based on the background and concepts provided by the course lecturers, delegates will apply this information to the WinNonlin modeling package. A unique feature of the course is the access to the computer package to undertake hands-on exercises on real-life case studies and availability of course tutors to help in problem solving. The participants will be exposed to a wide range of preclinical and clinical PKPD datasets based on single/multiple subjects.

LEARN ABOUT

- Basic pharmacodynamic theory
- Turnover concept and modelling theory
- Effect compartment models
- Receptor on/off binding models
- Pharmacodynamic complexities
- Single and multiple dose dynamics
- Inter-species scaling of PD data
- Tolerance & rebound models
- Transduction, Synergy
- How to apply quantitative pharmacology (PKPD) in discovery & development

OUTLINE PROGRAMME

DAY 1: INTRODUCTION TO QUANTITATIVE PHARMACOLOGY

Pharmacodynamics 1: Steady-state dynamics
Pharmacodynamics 2: Link/effect compartment
Hands-on exercises: Basic PD models, Link models
Numerical Grammar
Evening exercise on pattern recognition in PD data I

DAY 2: PHARMACODYNAMIC ISSUES

Pharmacodynamics 3: Indirect response I-IV: theory, initial estimates
Pharmacodynamics 4: Indirect response I-IV: complexities
Hands-on exercises: Indirect response I-IV single dose dynamics
Evening exercise on pattern recognition in PD data II

DAY 3: PHARMACODYNAMIC ISSUES

Pharmacodynamics 5: Modelling of transduction, synergy, irreversible responses
Pharmacodynamics 6: Functional adaptation/feedback/rebound and synergy
Group exercise: Integration of data from several subjects, experimental design
Hands-on exercises: Multiple dose dynamics, transduction, synergy
Evening exercise on pattern recognition in PD data

DAY 4: INTER-SPECIES SCALING

Pharmacodynamics 7: Allometric scaling of PKPD data
Hands-on exercises on scaling PK and PD data, multiple dose dynamics, transduction
Experimental Design
Computer Aided Trial Design





CONTENT & OBJECTIVES

Morning sessions consist of advanced lectures dealing with pharmacodynamic theory, interpretation of computer output, practical experimental design, discrimination between rival models and combining data of different sources. Afternoon/evening sessions are devoted to applying the methods discussed in the lectures to actual data using WinNonlin. Three evening exercises that wrap-up each topic are also included. The course will also include a group session about moving from data to insight and building conceptual models, which has been popular with delegates in previous years.

An extensive number of pharmacokinetic and pharmacodynamic models and real life data sets will be covered. Users of software other than WinNonlin would also benefit from the methods discussed in the lectures and hands-on sessions. This includes single and multiple dose dynamics, steady-state data, turnover (indirect response) models, link models, tolerance, rebound and synergistic models, bi-phasic response data, physiological kinetic/dynamic modelling, transduction models, diurnal variations, allometric models for scaling kinetic and dynamic data/parameters and antibody PKPD. Participants are strongly encouraged to bring their own kinetic/dynamic data.

Delegates will receive a comprehensive resource pack at the start of the course, which includes copies of all presentation material.

In addition, 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 18 February. Delegates registering after this date must order and pay for a copy of the book in advance of the course (details on how to purchase the textbook will be provided upon registration). This book provides an introduction into pharmacokinetic and pharmacodynamic concepts using simple illustrations and reasoning and describes ways in which pharmacokinetic and pharmacodynamic theory may be used to give insight into modelling questions and how these questions can in turn lead to new knowledge.

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 analyses & modelling, participants who attended the earlier introductory workshop, and researchers with a working knowledge of WinNonlin who want to learn more about the advanced features of the programme. Primary and safety pharmacologists will find the course beneficial.





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.

WHAT PREVIOUS DELEGATES HAVE SAID

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

"The teachers are very clear on every topic, which made it easy for us to feel comfortable with this rather intimidating material"

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

DELEGATES FEES

Delegate fees are £2365 or £2295 for members of the Royal Pharmaceutical Society or the Swedish Academy of Pharmaceutical Sciences. The fees are inclusive of four nights accommodation, meals and refreshments, a welcome reception, social programme and a resource pack with full course documentation. A few academic places are available at a reduced rate – please enquire for further details (reduced fees do not include a complimentary copy of the textbook).

IMPORTANT INFORMATION

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

CANCELLATION & REFUND

Should you find that you are not able to attend the residential course 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.





VENUE

Madingley Hall is an old country house set in the charming village of Madingley, situated approximately 3 miles from the University City of Cambridge.

Madingley is easily accessible by rail, road and air. Free car-parking facilities are available. The well-appointed study bedrooms have private bathroom/shower, telephone and tea/coffee making facilities.

Delegates are expected to register by approximately 17.00 on Sunday 18 May and the course will finish by approximately 16.00 on Thursday 22 May.

CHANGES TO THE PROGRAMME

The Royal Pharmaceutical Society will endeavour to present the programme as described. However, it reserves the right to make changes to the programme or speakers but will advise delegates of changes in advance. Should it be necessary to cancel the event, delegates will be advised as soon as possible and delegates will receive a full refund of fees paid. The Royal Pharmaceutical Society does not accept liability for any expenses incurred by delegates, including advance purchase travel tickets.





PKPD DATA ANALYSIS – 18-22 MAY 2008

REGISTRATION FORM

Delegates will be registered upon receipt of the completed form and will be liable to pay the fees.
Payment must be made before the start of the course.

PLEASE WRITE CLEARLY IN BLOCK CAPITALS

SURNAME

TITLE (Miss/Mrs./Ms./Mr./Dr./Prof.)..... FORENAME.....

ORGANISATION

ADDRESS

.....

.....

POST CODE TELEPHONE

FAX NUMBER EMAIL

MEMBERSHIP NUMBER

(if applicable)

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 our mailing list.

I have specific dietary requirements (please detail)

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Registration fees: £2295 for members of Royal Pharmaceutical Society or Academy of Pharmaceutical Sciences or £2365 for non-members (fees inclusive of 4 nights accommodation, meals and refreshments, a welcome reception, social programme, and a resource pack with full course documentation.)

☐ I am a member of the Royal Pharmaceutical Society or Swedish Academy of Pharmaceutical Sciences* (£2295)

☐ I am a non-member (£2365)

☐ I am registering before 18 February 2008 and claim a complimentary copy of the textbook





METHOD OF PAYMENT (payment must be made before the start of the course)

PLEASE DO NOT INCLUDE ANY OTHER PAYMENTS TO RPSGB

☐ Cheque in GB pounds sterling, made payable to "The Royal Pharmaceutical Society".

☐ Bank Transfer:

Sort Code 60 60 04 Account Number: 7037 8193. Quoting ref CAS SPR 401
National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB

☐ Credit Card

☐ Mastercard

☐ Visa

☐ Amex

Card Number: _ _ _ _ _

Security No. _ _ _

Expiry Date:...../...../.....

Signed:.....

VAT Registration Number: GB 233 0296 92. A VAT receipt will be issued on request.

CARDHOLDER'S NAME.....

ADDRESS.....

POSTCODE.....

PLEASE COMPLETE THE REVERSE SIDE OF THIS REGISTRATION FORM

ONE FORM PER PERSON PLEASE – PHOTOCOPIED FORMS ARE ACCEPTED

Please return this form with your payment to: Science Programme Manager, Royal
Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN
Fax: 020 7572 2506 Email: science@rpsgb.org (Tel: 020 7572 2261)

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