BII WORLD
Engage • Enlighten • Empower

PHARMACOKINETICS/PHARMACODYNAMICS
MODELLING
Concepts and Applications in Drug R & D

ONLINE LIVE SESSIONS

Join our global industry expert **Stefano Persiani** and transform your virtual learning experience.

06 - 09 May 2024

16 Hours Virtual Learning Experience
13:00 – 17:00 Central European Time

www.biiworld.com

Course Backdrop

The primary objective of modelling in pharmacokinetic studies is the prediction of the time course of the drug concentration in blood or other biological fluids and its relationship with the drug effect and with dose. Modelling has become a key success factor in drug R&D. PK/PD modelling represents and extremely useful tool for the selection of drug candidates, their optimization, and for maximal exploitation of early clinical studies for an optimal design of pivotal Phase 3 trials. PK/PD relies on prior in vitro bioassays, animal, and early clinical studies.

PK/PD modelling is part of pharmacometrics and can be based also on the patho-physiological mechanisms and progression of the disease to predict therapeutic effects. PKPD modelling leveraging from Physiologically-Based approaches (PBPKPD) allows the extrapolation of human data from animal studies to predict human dose and exposure in healthy subjects. Availability of disease progression models and pathophysiology data allows to further translate the prediction from healthy subjects to patients.

COURSE OVERVIEW:

This comprehensive and detailed intermediate 4-day online course describes the PK/PD studies from an industrial perspective to achieve a successful regulatory submission. The course is intended for those that do not have a previous background in PK/PD but also for those with experience in PK/PD but wish to get an in-depth training in PK/PD.

The course sessions will provide a review of the PK processes and of PD studies from a pharmacological perspective. Preclinical PK/PD studies including the role of radiolabelled studies and the evaluation of pharmacologically active and/or toxic metabolites and toxicokinetic will be described. The dose-exposure-effects will be explained through mechanism-based and physiologically-based PK/PD modelling to design first-in human and later clinical trials. Clockwise and counter-clockwise hysteresis as common forms of PK/PD correlations will be covered as well as the use of biomarkers to assess target occupancy and their difference from surrogate endpoints.

The application of MRSD and MABEL approaches and micro dosing as regulatory requirements and tools for a correct design and conduction of early clinical trials, will be explained. Biological and advanced therapies are becoming more important, and the course will provide an overview of PK/PD studies for these new agents. The scientific background, study design, and data interpretation for population pharmacokinetics will be covered. Finally, the course will describe how the potential for a NCE to exert drug-drug interaction is assessed in pre- and clinical development.

Population PK is another highly powerful modelling approach to predict the exposure of a subject (either healthy or diseased) based on covariates that will affect the time course of the plasma concentrations at different doses. It therefore allows to predict the time course of exposure in a given patient based on its characteristics such as body weight, age, etc. using the population mean exposure time course. The course will provide the basic concepts and application of Population PK as well as its relevance in drug R&D, Case studies will also be provided.

THE COURSE PROVIDES:

Participation will provide an overview of the above topics including temporal placement throughout the drug R&D program. This will be done without excessive use of mathematics. The course will provide trouble-shooting strategies for all the main studies and will focus on the critical aspect for a smooth conduction, interpretation, and use of PK/PD for the successful selection and registration of New Chemical and Biological Entities.

- Live interactive bitesize sessions
- Real-time access to a subject matter expert delivering online training in a structured virtual classroom environment
- Participation in interactive features within sessions including polls, Q&A, break out rooms, tasks, case studies and more

LEARNING OBJECTIVES:

By the end of this intensive course, you will get:

- A deeper understanding of the PK/PD studies in drug R&D from an industrial perspective.
- A deeper insight into the optimal strategies to design and interpret the relevant PK/PD studies.
- A detailed appreciation of the role of biomarkers in drug R&D and their optimal use for study design and outcome evaluation.
- A critical and practical overview of the crucial aspects of the first in human study design, conduction, and interpretation including regulatory aspects.
- Insights on how to avoid failure of PK/PD studies conducted either in-house or contracted externally.
- A detailed appreciation on the differences between small molecules and biological and advanced therapies as far as PK/PD are concerned.
- A deep coverage of how drug interaction occurs and how to predict them during drug R&D.

AUDIENCE (Who should attend?):

This course has been specifically designed to address the needs and will be of particular benefit to professionals working in different departments including:

- Pharmacokinetics
- Pharmacology
- Regulatory
- Medical Affairs
- Licensing
- Project Management
- Outsourcing
- Pre-clinical Discovery and Development
- Clinical Research and Development

Instructor: Stefano Persiani

Dr. Stefano Persiani is currently Director of Translational Sciences and Pharmacokinetics at Rottapharm Biotech, Italy. He graduated in Pharmacy at the University of Milan, Italy and completed a post-doctoral fellowship in the Department of Pathology of the University of Pittsburgh, School of Medicine, Pittsburgh, Pennsylvania, USA, and later as a Research Associate in the Department of Pharmaceutics of the University of Southern California, School of Pharmacy in Los Angeles, California, USA. He entered the pharmaceutical industry at Farmitalia Carlo Erba, Pharmacia, Upjohn, and Zambon Group and in the CRO sector with different managerial roles in drug R&D.

Dr. Persiani is currently applying translational approaches from drug discovery to development and registration in several therapeutic areas. He is a member of various international scientific societies and serves on the review board of numerous professional journals.

Dr. Persiani acts as an external expert evaluator for the European Commission on the 7th Framework Program, Maria Sklodowska-Curie Individual Fellowships, HORIZON 2020, and Innovative Medicine Initiative, and for several other government organizations where he evaluates and provides recommendations on applications requesting funding.

Dr. Persiani has many years of teaching and training experience in several fields of Translational Sciences. Dr. Persiani experience consists in translational approaches for drug discovery and development for successful drug discovery and development. Regulatory pre-clinical development package and early clinical development.

PRESENTATIONS:

DAY1 13:00 - Pre-Course

Module 1

Foundation of Pharmacokinetics

- Absorption, Distribution, Metabolism and Excretion.
- Relationship between clearance, volume of distribution and half-life.
- Critical aspects in relation to PK/PD, tissue
- PK after oral/intravenous dosing.
- PK after single/repeated doses.
- Superposition principle.
- Study design, results interpretation and relevance for PK/PD.

Break

Module 2

ADME studies in Animals and Man

- Critical issues in study design and interpretation.
- Total circulating radioactivity vs unchanged drug.
- Metabolite identification and its relevance in PK/PD.
- Toxicokinetics.
- Metabolites in safety testing (MIST) and FDA guidance.

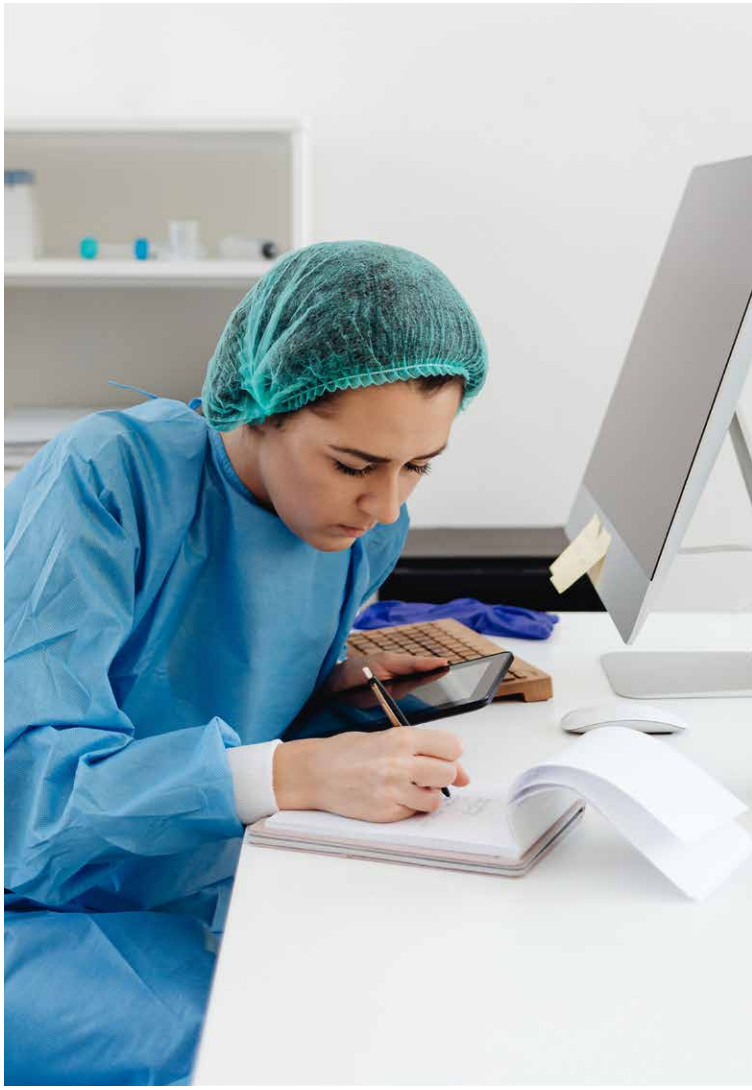
Break

Interactive Exercise – 1:

- Case Study selections of a lead candidate
- Translation from animal data to human
- Comparison with benchmarks products during discovery

Post-Course Q &A

17:00 – End of Day1



Module 3

Drug-drug Interactions

- Enzyme identification (reaction phenotyping).
- Enzyme induction.
- Enzyme inhibition.
- Role of transporters. Relevance and pitfalls during the interpretation of the results.
- Study design for prediction of clinically relevant drug-drug interactions. Data presentation and interpretation
- Regulatory submission and labelling.

Break

Module 4

Foundation of Pharmacodynamics

- Drug-receptor interaction.
- Dose-response curve. Relevant pharmacological parameters
- Potency/efficacy.
- Receptor occupancy.
- Relevance of plasma protein binding in pharmacological effects.
- Therapeutic index and window.

Break

Module 5

Biomarkers

- Classification of biomarkers.
- Biomarkers and surrogate endpoints.
- Selection, validation, and qualification of biomarkers in preclinical and clinical studies.
- FDA guidelines on pharmacogenomics and exposure-response.

Break

(Case Study 1): The use of biomarkers in preclinical and clinical development.

Module 6

PK/PD Correlation and Modelling

- PK, PD and their correlation and drug-exposure-effect continuum in drug R&D.
- Physiologically-based pharmacokinetic (PBPK) and pharmacodynamic (PBPKPD) modelling
- Mechanism-based pharmacokinetic and pharmacodynamic modelling for dose selection and to predict the outcome of clinical trials.
- Clockwise and counterclockwise hysteresis as common forms of PK/PD correlations.

Break

Module 7

Special considerations for PK/PD of biological and advanced therapies

- Description of biological and advanced therapies.
- Difference between small molecules and biological and advanced therapies.
- PK of ADCs, bispecific, and Fc engineered monoclonal and multispecific antibodies.
- Regulatory requirements for the assessment of PK and PK/PD.

Break

Interactive Exercise – 2:

- Case Study of the use of imaging CNS indications
- Case Study in oncology from animals to man

Post-Course Q &A

17:00 – End of Day3

Module 8

PK/PD in First in human trials and later clinical trials

- PK/PD during the selection of the starting dose, dose escalation and study design.
- Target occupancy and effect of plasma protein binding.
- Toxicology and MRSD for the design of first in human trials.
- MABEL approach for the design of first in human trials.
- Regulatory requirement for study approval and crucial issues for a correct study conduction.
- Microdosing
- Dose-exposure-effect in Proof of Concept (POC) studies in patients.

(Case Study 2): PKPD modelling in non-oncologic indications.

(Case Study 3): PBPKD modelling in oncology

Module 9

Population Pharmacokinetics

- Concepts and applications
- Relevance in drug development
- Non-linear mixed effect modelling
- Observed vs predicted values
- Case Study: Population PK study design and interpretation
- Case Study: Developments of anti-infectives application of population PK with the aid of different matrices and samples

Post-Course Q &A (Day1-4)

17:00 – End of Day4 and Course

FAQs

Does BII Online Virtual Training have the same value as traditional classroom training?

Yes, BII Online Virtual Training offers participants; same training system as in-person, i.e face-to-face engagement with instructors, course material, interactive participation of all delegates, and personal support that they would expect to find in a traditional classroom.

What are main features of your online courses? Are they on-demand? Is it different content from the in-person offering?

The content of the virtual training is similar to the in-person sessions and customized presentation makes it a richer online learning experience. As always, we will share presentation materials with attendees for later reference.

The online courses are not on-demand and recordings cannot be purchased. They are set on scheduled dates, live with an instructor and co-host via webinar software. While the day is shorter than an in-person session (4hrs vs 8hrs), timing are adjusted to accommodate attendees in different time zones and allow more time for one-on-one conversations via the Q & A.

What are the technical requirements for participation in a virtual course?

All you need to participate in virtual training are:

- Desktop or Laptop or Tablet Computer, and Internet connection
- Webcam
- Headset with built-in microphone

Can I attend an online training session if I have a Macintosh computer?

Yes, Our Online training systems does allow Macintosh computers, PCs, and computers running Linux to easily enter any of our online training sessions.

What type and version of browser will I need for online classes?

It is recommended that you use the latest version of Firefox, Chrome or Internet Explorer for Windows and Firefox or Safari for Mac. Each of these is available for free download and also suggested you have the PDF Reader

How do I have access to the trainer for questions?

As in the classroom, you will see the trainer in front of you and have the opportunity to ask questions at any time - all via audio and video transmission.

Is there a mute option within an online training session to minimize background noise from my audio connection?

Yes, the Mute button will display to the right of your name as you hover your mouse over your name shown in the Participants panel on the top, right side of the Web conferencing screen.

What if I miss few sessions of the online training program?

The training will be simultaneously recorded which will be provided to you as per request & requirement

Do I get a Certificate at the end?

Yes, you will get a PDF version of your certificate of completion

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06 - 09 May 2024

BII World Limited
9616 45th Avenue
Northwest, Edmonton, AB
T6E 5Y9, **Canada**

Please complete this form and mail it back to
sarodh.panicker@biiworld.com

Event Code: EU LS 41

Delegate Details

1. Name: Mr/Mrs/ Ms .....
   .....
   Job Title: .....
   Email: .....
2. Name: Mr/Mrs/ Ms .....
   .....
   Job Title: .....
   Email: .....
3. Name: Mr/Mrs/ Ms .....
   .....
   Job Title: .....
   Email: .....

Company/Organisation Detail

Name: .....
Person to Contact:.....
Email: .....
Address: .....
.....
City: .....
Country: .....
Contact No: .....
Type of Business: .....
Website: .....

Payment Details

METHOD: CREDIT CARD ☐ OR WIRE TRANSFER ☐

Please debit my

Visa ☐ Eurocard /Mastercard ☐ Amex ☐ Diners club ☐

Card Billing Address:.....
Street: .....City.....
Zip/Postal: .....
Card Holders Name: .....
Email Address: .....
Card Holders Signature: .....
Card Number

Credit Card CVV2/ CVC / CID Number:

Visa / Mastercard (3-digit code on the back) ☐☐☐ Amex (4-digit code on the front) ☐☐☐☐

Valid from: ☐☐ / ☐☐ Expiry Date: ☐☐ / ☐☐

I agree to BII debiting my card

Authorization and Acceptance of Sales Contract & Terms & Conditions

I hereby declare I am authorised to sign this contract and terms & conditions in the name of the company/organisation:

Name:.....
Date:.....
Signature:.....

Delegate Fee ☐ **EUR 1299** Per Delegate

Delegate Fee ☐ **EUR 1099*** Per Delegate

***(Early Bird until Nov 30th, 2023)**

EUR 20 administration charge and any applicable withholding or any other tax or fee will be applied

TERMS & CONDITIONS:

1. Payment terms: BII World LTD requires the full payment of the invoiced amount within 7 working days from the issue date of the invoice. BII World LTD reserves the right to refuse entry to any client who does not pay the invoice in full and on time. The registration fee includes: Training documentation and admission to all training sessions.

2. Cancellation by client: The client has the right to cancel his/her participation in the event. Cancellation must be received by BII World LTD in writing either by mail or fax. If the client cancels the event, he/she will get two options:

A. CREDIT NOTE: Choose 2-year credit note, BII World LTD will send all the schedule training event details throughout the year. Delegate has the right to choose and attend any of the training programs (valid 2 years).

B- NOMINATION: In this option delegate can nominate/refer someone from his/her group/company to attend the particular training program on behalf of the actual delegate.

3. Cancellation by BII World LTD : While every reasonable effort is made to adhere to the advertised program, circumstances can arise which may cause changes in the program, including but not limited to changes in the content, date(s), or special features of the planned event. Such circumstances include but are not limited to acts of terrorism, war, extreme weather conditions, compliance with government requests, orders and legal requirements, failure of third-party suppliers to timely deliver, and failure to register the minimum target number of attendees for a given event. BII World LTD reserves the right to change the content, date(s), and/ or special features of an event, to merge the event with another event, or to postpone it or cancel it entirely as appropriate under the circumstances. Client agrees that BII World LTD shall not be liable for any cost, damage or expense which may be incurred by client as a consequence of the event being so changed, merged, postponed or cancelled and client agrees to hold BII World LTD harmless and to indemnify BII World LTD in case of liability caused by any such changes, mergers, postponements or cancellations.

4. Cancellation of the event: In case BII World LTD cancels an event, then client can choose any of the below mentioned options:

(a) BII World LTD will refund full payment to the client within 15 business days.
(b) Client can choose the credit option for 2 years, for more details please read term no-2 part (a)

5. Postponement of the event : In case BII World Ltd postpones the event to a new date, then client can choose any of the below mentioned options.

(a) The client can attend the course on the postponed dates.
(b) Client can choose the credit option for 2 years, for more details please read term no-2 part (a)

6. Client's identification information. By signing of this sales contract and these terms and conditions the client gives full right to BII World LTD to share the client's identification information, i.e. client's name, address, email addresses, phone numbers and names of representatives and website with other clients who participated in the same event. The client has the right to opt out of this clause by written notice to BII World LTD.

7. Governing law: This contract shall be governed by and construed in accordance with the laws of the Pr ovince of Alberta, Canada. Any disputes arising under or in connection with this registr ation form shall be settled before the competent court in Canada.

8. Indemnification: To the fullest extent permitted by the law, you agree to protect, indemnify, defend and hold harmless BII World LTD, its owners, managers, partners, subsidiaries, affiliates, officers, directors, employees and agents, from and against any and all claims, losses or damages to persons or property, governmental charges or fines, penalties, and costs (including reasonable attorney's fees) (collectively "the Claims"), in any way arising out of or relating to the event that is the subject of this contract, and regardless of negligence, included but not limited to, Claims arising out of the negligence, gross negligence or intentional misconduct of BII World LTD employees, agents, contractors, and attendees; provided, however, that nothing in this indemnification shall require you to indemnify BII World LTD Indemnified parties for that portion of any Claim arising out of the sole negligence, gross negligence or intentional misconduct of the BII World LTD parties.

9. Other currencies. In case that client requests payment in other than official currency (USD), BII World LTD reserves the right to apply 5% currency risk surcharge to the actual exchange rate.

10. Other Conditions: Any terms or conditions contained in the client's acceptance which contradict or are different from the terms and conditions of this registration document shall not become part of the contract unless individually negotiated with BII World LTD and expressly accepted by BII World LTD.