

25th Pharmacokinetics/Pharmacodynamics (PK/PD) Expert Meeting, Nauen, April 20th-22nd, 2023



Agenda

Thursday, April 20th, 2023

17:00 – 19:00	Arrival Landgut Stober Behnitzer Dorfstraße 27-31 14641 Nauen, OT Groß Behnitz
19:00	Dinner

Friday, April 21st, 2023

08:30 Welcome
Corina Becker & Joachim Höchel on behalf of the Organizing Committee

Session 1: Drug-drug interactions– What's new in 2023?

Session Chairs: Thorsten Lehr, Tobias Pähler

08:40 ICH M12 / EMA / FDA – new guidelines & resulting implications
Sheila Peters, Boehringer Ingelheim, Germany

09:10 *Discussion*

09:25 PBPK Modeling of drug-drug interactions – techniques & regulatory acceptance
Stephan Schaller, esqLABS GmbH, Germany

09:55 *Discussion*

10:10 Coffee Break

10:45 Replacement of rifampicin as strong CYP3A inducer – the industry experience
Thomas Gießman, Boehringer Ingelheim, Germany & Tommaso Fadini, Bayer AG, Germany

11:15 *Discussion*

11:30 Drug-drug interactions with therapeutic proteins and peptides
Antoine Deslandes, Sanofi, France

12:00 *Discussion*

12:15 Joint Lunch

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Session 2: Translation to and from patients – Current concepts to address the challenge

Session Chairs: Alexander Staab, Corina Becker

- 13:30 Translation 4 Patients – The translational sciences framework at Boehringer Ingelheim
Jens Borghardt, Valerie Nock, Boehringer Ingelheim, Germany
- 14:00 *Discussion*
- 14:15 Project Optimus: Implications for drug development
Jeffrey Stuart, MSD, United States (remote)
- 14:45 *Discussion*
- 15:00 Finding the needle in the haystack in oncology Phase I trials - what's next in translational PKPD?
Antje Walz, 3T Biosciences, Switzerland
- 15:15 *Discussion*
- 15:25 ICH Guideline Development on Model-Informed Drug Development - Update from the M15 Expert Working Group
Jörg Lippert, EFPIA Deputy Topic Lead
- 15:45 Coffee Break
- 16:15 Hans Günter Schäfer Award
Moderated by Joachim Höchel
- 16:45 25 PK/PD Expertentreffen – ein persönlicher Rückblick
Wolfgang Mück, formerly Bayer AG, Germany (Presentation will be held in German.)
- 17:10 End of Session
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17:45 Joint Jogging

19:30 Dinner

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Saturday, April 22nd, 2023

Session 3: Drug development for brain diseases – New Approaches

Session Chairs: Antje Walz, Charlotte Kloft

- 09:00 Central nervous system PK/PD research – status quo: Challenges and opportunities
Elizabeth de Lange, Leiden Amsterdam Centre for Drug Research (LACDR), The Netherlands
- 09:20 *Discussion*
- 09:30 The Leiden CNS PBPK (LeiCNSPK) models to predict CNS drug distribution, integrating all PK processes involved
Elizabeth de Lange, LACDR, The Netherlands
- 09:50 *Discussion*
- 10:00 Coffee Break
- 10:30 Advanced modalities to treat neurodegenerative disease: Cell-based therapy for Parkinson's disease
Stefan Irion, BlueRock Therapeutics, USA
- 11:00 *Discussion*
- 11:15 New conceptual approaches for mental diseases: precision psychiatry
Joachim Scholpp, Boehringer Ingelheim, Germany
- 11:45 *Discussion*
- 12:00 Closing Remarks
Corina Becker & Joachim Höchel on behalf of the Organizing Committee
- 12:05 Joint Lunch
- 13:00 End of Meeting
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