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Jens Rengelshausen, Barbara Schug, Georg Wensing

Venue

Kardinal-Wendel-Haus
Mandlstraße 23 | 80802 Munich (Germany)

Dates

25 April 2018 Pre-Workshop
26 & 27 April 2018 Annual Meeting

A certification by the Landesärztekammer is requested.

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The Association for Applied Human Pharmacology (AGAH) is a scientific medical non-profit organisation which members work in the field of explorative drug development and human pharmacology. The organisation is particular open for professionals who work in the field of translational medicine i.e. bringing new medicinal products from the bench into clinical research.

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Human Pharmacology

27th AGAH Annual Meeting

TARGET ORGANS IN EARLY MEDICINES DEVELOPMENT - PREDICTABILITY AND PREVENTION OF ADVERSE REACTIONS

25 April 2018 Pre-Meeting-Workshop

26 - 27 April 2018

Kardinal-Wendel-Haus | Munich (Germany)

Programme

Wednesday, 25 April 2018

Pre-Workshop
Pharmacovigilance in early phase drug development – basic terms and key concepts
Chairs: K. Breithaupt-Groegler, Frankfurt (Germany)
K. Erb-Zohar, Hanau (Germany)

13:00 – 13:45 Identification, assessment, and communication of adverse events in (early phase) clinical trials
A. Blank, Heidelberg (Germany)

13:45 – 14:30 Identification of risks - Key documents on safety information (Investigator's brochure, company core data sheet, company core safety information, summary of product characteristics, risk management plan, development safety update report, periodic safety update report/ periodic risk-benefit evaluation report)
M. Weber, Ingelheim am Rhein (Germany)

14:30 – 14:45 Break

14:45 – 15:05 Useful tools for the evaluation of adverse events (CTC-AE, designated AEs, EMA list of important medical events)
K. Erb-Zohar, Hanau (Germany)

15:05 – 15:45 Management of safety signals in early phase drug development
U. Vogel, Ingelheim (Germany)

15:45 – 16:15 »Safety Review Committee« in early phase trials
J. Graff, Frankfurt (Germany)

16:15 – 16:30 Break

16:30 – 17:45 Stop dose escalation or continue dosing? - Case study developed in break-out groups
K. Erb-Zohar, Hanau (Germany)

17:45 – 18:00 Wrap up and end of meeting

18:15 Get together

19:00 AGAH General Assembly

Day 1 | Thursday, 26 April 2018

08:45 Welcome
B. Schug, Oberursel (Germany)

09:00 Hypersensitivity reactions and adverse drug reactions
Sir Munir Pirmohamed, Liverpool (United Kingdom)

Session 1 **Drug-induced renal function impairment**
Chairs: M. Boettcher, Wuppertal (Germany)
J. Rengelshausen, Aachen (Germany)

09:45 – 10:15 Relevant new renal function biomarkers?_P. Murray, Dublin (Ireland)
10:15 – 10:45 Renal function in early phase trials _M. Boettcher, Wuppertal (Germany)
10:45 – 11:15 Break

Session 2 **Drug-induced liver injury**
Chairs: S. Plassmann, Munich (Germany);
G. Wensing, Wuppertal (Germany)

11:15 – 11:45 Safety assessment of hepatic findings in non-clinical studies
S. Plassmann, Munich (Germany)

11:45 – 12:15 Findings on hepatic function parameters in early phase trials with healthy subjects_D. Jung, Wuppertal (Germany)

12:15 – 12:45 Clinical interpretation of hepatic safety biomarkers
M. Merz, Zurich (Switzerland)

12:45 – 13:00 Discussion

13:00 – 14:00 Break

Session 3 **Drug-induced CNS adverse reactions**
Chairs: F. Donath, Erfurt (Germany); J. Stingl, Bonn (Germany)

14:00 – 14:30 Preclinical screening for CNS effects of potential drug substances
M. Traebert, Basel (Switzerland)

14:30 – 15:00 Physico-chemical drug properties and human CNS system characteristics: determinants of CNS pharmacokinetics at different locations in human brain_E. de Lange, Leiden (The Netherlands)

15:00 – 15:30 Prediction and detection of off-target drug effects on mental health: from neuronal cell models to neuroimaging_J. Stingl, Bonn (Germany)

15:30 – 15:45 Discussion

15:45 – 16:15 Break

Session 4 **Drug-induced adverse cardiac reactions**
Chairs: M. Iovino, Biberach (Germany)
J. Taeubel, London (United Kingdom)

16:15 – 16:45 Influence of contractility of cardiomyocytes – pathophysiology of cardiac muscle toxicity_U. Ravens, Freiburg i. Breisgau (Germany)

16:45 – 17:15 QTc assessment strategies in early phase development
B. Darpo, Stockholm (Sweden)

17:15 – 17:45 Waivers on TQT trials – a critical appraisal = Expert panel discussion with S. Baumann, Berlin (Germany); B. Darpo, Stockholm (Sweden); N. Beetz, Biberach (Germany); D. Kubitza, Wuppertal (Germany); J. Taeubel, London (United Kingdom)

19:30 Conference - Networking - Dinner

Day 2 | Friday, 27 April 2018

Session 5 **Local tolerance in drugs intended for alternate routes of administration**
Chairs: E. Roehrdanz, Bonn (Germany)
B. Schug, Oberursel (Germany)

09:00 – 09:30 Non-animal research models: imitation of three-dimensional cavities for risk assessment in respiratory tract
S. Constant, Geneva (Switzerland)

09:30 – 10:00 Risk assessment for dermal application: how to estimate skin irritation and sensitisation from animal and in-vitro data
D. Basketter, Sharnbrook (United Kingdom)

10:00 – 10:30 Guideline on non-clinical local tolerance testing of medicinal products: regulatory perspectives
E. Roehrdanz, Bonn (Germany)

10:30 – 10:45 Discussion

10:45 – 11:15 Break

Session 6 **Immunotoxicity**
Chairs: C. Coch, Bonn (Germany)
J. Descotes, Lyon (France)

11:15 – 11:45 Immunological safety issues in early clinical trials: a translational approach
J. Descotes, Lyon (France)

11:45 – 12:15 Challenges and approaches for predicting immunogenicity
P. Mayer, Bonn (Germany)

12:15 – 12:55 Safety and immunogenicity for Gene Therapy Medicinal Products and Therapeutic Vaccines
M. Goldammer; N. Kirsch-Stefan, Langen (Germany)

12:55 – 13:10 Discussion

13:10 Concluding remarks
G. Wensing, Wuppertal (Germany)

13:20 Farewell

subject to modifications, status February 2018