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Concepts & Solutions in Drug Development

DDI 2013

4th International Workshop on Regulatory Requirements and Current Scientific Aspects on the Preclinical and Clinical Investigation of Drug-Drug Interactions

ACCP
DGRA
DMDG DRUG METABOLISM discussion group
member of BioLAGO life science network

May 26th to 28th, 2013
Marbach Castle, Germany

Second Announcement

MISSION STATEMENT

The overall objective of the International Marbach Castle DDI Workshop series is to enhance and disseminate the scientific knowledge about drug-drug interactions (incl. food-drug and herb-drug interactions), to foster the most appropriate preclinical and clinical investigation and communication, thereby improving the safe use of drugs in the light of ageing populations and increasing poly-pharmacotherapy.

BACKGROUND, SCOPE AND AIM

In June 2010, the 1st International Workshop on Regulatory Requirements and Current Scientific Aspects on the Preclinical and Clinical Investigation of Drug-Drug Interactions took place. The workshop was based on an initiative of experts from academia and industry, intrigued by the notion that the field of drug-drug interactions (DDIs) is getting increasingly important and complex in view of continuously emerging new therapies, new drug combinations, complex treatment algorithms for many widespread disease states and ageing populations in the industrialized countries. These factors converge into a frequently employed poly-pharmacotherapy with increasing risk of clinically significant DDIs. Therefore, the meticulous investigation, informative labeling, and early recognition of DDIs represent substantial challenges for the pharmaceutical industry and regulatory bodies in the development, approval and post-marketing surveillance of new medicines. Failures in the early recognition, mechanistic elucidation (understanding) and proper clinical management of DDIs, in turn, have resulted in numerous drug withdrawals from the market in the past and continue to result in a significant health burden to patients as well as an economic burden on healthcare systems, rendering many DDIs serious public safety concerns.

Today, DDIs can be addressed in a more targeted and evidence-based fashion, because considerable progress has been made in the understanding of the underlying mechanisms of DDIs and the subsequent development of methodologies for the investigation of DDI susceptibility, and the extrapolation of outcomes of particular DDIs to other drug combinations. Apart from metabolism based DDI, transporter based DDIs, DDIs involving therapeutic proteins as well as tools extrapolating *in vitro* results to predict clinical outcomes *in vivo* (IVIVE) have gained more importance over recent years. Furthermore, pharmacodynamic DDIs have gained increasing interest given the steady increase in drug combinations in clinical development.

The 2010 Workshop combined a regulatory update on the investigation of DDIs from the European Rapporteur perspective (MPA, Sweden) along with a scientific update focusing on the investigation of metabolism- and transporter-based DDIs. The 2011 Workshop focused on large molecule DDIs, non-metabolic DDIs affecting drug absorption as well as complex DDIs in selected therapeutic areas such as oncology, cardiovascular disorders as well as immunosuppressant and, anti-infective therapies. The 2012 Workshop comprised an introduction on the FDA's DDI Guidance in addition to DDIs based on UGT enzymes and hepatic transporters.

The Workshop is limited by concept to 70 participants from pharmaceutical industry, contract research organizations and drug regulatory agencies to provide a unique opportunity for scientific exchange and networking across company and organizational boarders, and to learn about the current state-of-the-art in the investigation of DDIs. Experts from more than 10 European countries and the United States participated in each of the three events. Based on the detailed feedback received from the Workshop audience, the structure and content of this Workshop was designed with particular emphasis on a variety of clinical, epidemiological, and population aspects of DDIs. The topics of the 4th International DDI Workshop will be covered by distinguished international scientists and experts from academia, pharmaceutical companies, contract research organizations, consultancies as well as government and regulatory agencies.

The Workshop Organizers

Hartmut Derendorf, PhD, FCP
Robert Hermann, MD, FCP
Amin Rostami-Hodjegan, PhD, FCP
Oliver von Richter, PhD, FCP

BENEFITS IN ATTENDING

- **Find out** how DDI signal detection and hypotheses generation is extracted from large clinical databases
- **Get informed** about the final EMA guideline on drug interactions
- **Focus** on drug interactions involving anti-infective drugs
- **Update yourself** on drug interactions involving therapeutic biologics
- **Discover** the different approaches for *in vitro in vivo* extrapolation of CYP inhibition data
- **Learn** about the optimal design of DDI trials in patient populations
- **Enhance** your knowledge about *in vitro* approaches in the assessment of CYP induction
- **Realize** important aspects linked DDIs in the geriatric population
- **Exchange** views on DDI related questions in the Q&A / polling sessions
- **Understand** how mechanistic PBPK modeling can aid in the investigation of pediatric DDIs
- **Gain** insights large scale evaluation of drug interactions in clinical practice
- **Get introduced** into post-marketing surveillance of DDIs
- **Learn more** about the need for translational research in the evaluation of DDIs
- **Meet, discuss and network** with scientific and regulatory experts from pharmaceutical- and contract research-industries, international regulatory bodies (EMA, MHRA), the International Transporter Consortium and academia

WORKSHOP PROGRAMME

May 26th, 2013

Sunday

Afternoon	Individual Arrival & Check-in at Marbach Castle
03:00 p.m.	Registration & Coffee
04:00 p.m.	Come Together Activities
08:00 p.m.	Come Together Dinner *Welcome address by Parliamentary State Secretary Helge Braun, MD; Federal Ministry of Education and Research, Berlin, Germany*

May 27th, 2013

Monday

08:00 – 09:00 a.m.	Registration & Coffee
09:00 – 09:15 a.m.	Welcome Address and Introduction into the Workshop *Robert Hermann, MD, FCP; cr.appliance, Germany*
09:15 – 10:00 a.m.	Key Note Lecture I Drug Interactions Involving Therapeutic Biologics – What We Need to Know *Bernd Meibohm, PhD, FCP; College of Pharmacy at the University of Tennessee, Memphis, United States*
10:00 – 10:15 a.m.	Discussion
10:15 – 10:45 a.m.	Coffee Break
	Session I: **Clinical, Epidemiological & Pharmacovigilance Aspects of DDIs** Chair: Robert Hermann
10:45 – 11:15 a.m.	The Need for Translational Research on Drug–Drug Interactions *Sean Hennessy PharmD, PhD; University of Pennsylvania, United States*
11:15 – 11:25 a.m.	Discussion
11:25 – 11:55 a.m.	Clinical Relevance and Large Scale Evaluation of Drug Interactions in Clinical Practice *Stefan Russmann, MD; University Hospital Zurich, Switzerland*
11:55 – 12:05 p.m.	Discussion

Session I:
Clinical, Epidemiological & Pharmacovigilance Aspects of DDIs (ctd.)

Chair: Robert Hermann

12:05 – 12:35 p.m.	Post-Approval Impact of Pre-Approval Approaches to DDIs – The Regulatory Perspective *Terry Shepard, PhD; Medicines and Healthcare Products Regulatory Agency (MHRA), London, United Kingdom*
12:35 – 12:45 p.m.	Discussion
12:45 – 02:00 p.m.	Lunch
02:00 – 02:45 p.m.	Key Note Lecture II The Final EMA Guideline on Drug Interactions and the Evolution of Regulatory Concepts and Requirements *Eva Gil Berglund, PhD; Medicinal Product Agency (MPA), Uppsala, Sweden*
02:45 – 03:00 p.m.	Discussion

Session II:
Novel Approaches to Improve the Prediction of DDIs

Chair: Amin Rostami-Hodjegan

03:00 – 03:30 p.m.	DDIs: FDA Guideline and Industrial Perspective and Challenges *Odette A. Fahmi, PhD; Pfizer Inc., Global Research & Development, Groton, United States*
03:30 – 03:45 p.m.	Discussion
03:45 – 04:15 p.m.	Lost in Extrapolation: Basic, Mechanistic and Dynamic Models to Assess the Need of an *In Vivo* Follow-up Trial from *In Vitro* CYP Inhibition Data *R. Scott Obach, PhD; Pfizer Inc., Global Research & Development, Groton, United States*
04:15 – 04:30 p.m.	Discussion
04:30 – 04:45 p.m.	Coffee Break

Polling Session

04:45 – 06:00 p.m.	Polling Session of Plenary Lectures and Sessions I and II *Moderators: Andrew Parkinson, PhD; Oliver von Richter, PhD FCP*
07:30 p.m.	Dinner
08:30 p.m.	Acoustic Guitar Concert – Simon Wahl (Fingerstyle Guitar) and Guest

May 28th, 2013

Tuesday

07:00 – 08:30 a.m.	Breakfast
08:30 – 09:15 a.m.	Key Note Lecture III Clinical Prospective of Important Drug-Drug Interactions in Infectious Diseases *Keith A. Rodvold, PharmD, FCCP, FIDSA;* *University of Illinois, Chicago, United States*
09:15 – 09:30 a.m.	Discussion
	Session III: **Drug-Drug Interactions Involving Anti-Infective Agents** Chair: Oliver von Richter
09:30 – 10:00 a.m.	DDIs Involving Anti-Viral Agents, with Particular Emphasis on HIV and Hepatitis C *David J Back PhD; University of Liverpool, United Kingdom*
10:00 – 10:15 a.m.	Discussion
10:15 – 10:45 a.m.	Coffee Break
10:45 – 11:15 a.m.	DDIs Involving Antibiotic Agents *Hartmut Derendorf PhD, FCP; University of Florida, Gainesville, United States*
11:15 – 11:30 a.m.	Discussion
11:30 – 12:00 a.m.	Time and Concentration Dependent DDIs Involving Anti-Fungal Agents *Gerd Mikus MD; University of Heidelberg, Germany*
12:00 – 12:15 p.m.	Discussion
12:15 – 01:30 p.m.	Lunch

Session III:
Drug-Drug Interactions Involving Anti-Infective Agents (ctd.)

Chair: Oliver von Richter

01:30 – 02:15 p.m.	Key Note Lecture IV Drug-Drug Interactions in Special Populations – Going Beyond Healthy Subjects *David J. Greenblatt, MD; Tufts University, Boston, United States*
02:15 – 02:30 p.m.	Discussion

Session IV:
Going Beyond Healthy Subjects – DDI in Special Populations

Chair: Hartmut Derendorf

02:30 – 03:00 p.m.	Design of DDI Trials in Special Populations *Lisa von Moltke MD, FCP; Genzyme, Cambridge, United States*
03:00 – 03:10 p.m.	Discussion
03:10 – 03:40 p.m.	Forgotten Population – DDIs in the Pediatrics *Amin Rostami-Hodjegan PhD, FCP; University of Manchester, United Kingdom*
03:40 – 03:50 p.m.	Discussion

Q & A Session

03:50 – 04:45 p.m.	Q & A Session Involving all Workshop Topics *Moderators: Hartmut Derendorf PhD, FCP; Amin Rostami-Hodjegan PhD, FCP*
04:45 – 05:00 p.m.	Concluding Remarks *Robert Hermann, MD, FCP; cr.appliance, Germany*
05:00 p.m.	End of Meeting & Individual Departure

WHO SHOULD ATTEND?

This international Workshop on drug-drug interactions is designed to meet the requirements and expectations of professionals from the pharmaceutical industry, contract research organisations, regulatory agencies and academia.

Department heads, project managers, scientists and consultants in R&D, in regulatory affairs, pharmacokinetics, clinical pharmacology, exploratory/translational medicine, clinical development, drug safety, biostatistics, business development, medical communications and so forth should attend. All delegates are invited to contribute actively to the scientific discussions.

LANGUAGE

English will be the language of the Workshop. No simultaneous translation will be provided.

VENUE & LOCATION

The Workshop will take place at the Marbach Castle Conference Centre (see the following web site: www.schlossmarbach.de), located close to the Swiss border amidst the beautiful surrounding of the Western shore of Lake Constance in close proximity to the historic town of Stein am Rhein. The old town centre of Stein am Rhein is characterised by striking medieval buildings such as the City Church, the former Monastery of St. Georgen, burghers' houses, gates and towers, as well as buildings dating from the early modern age, including the Town Hall and the Arsenal.

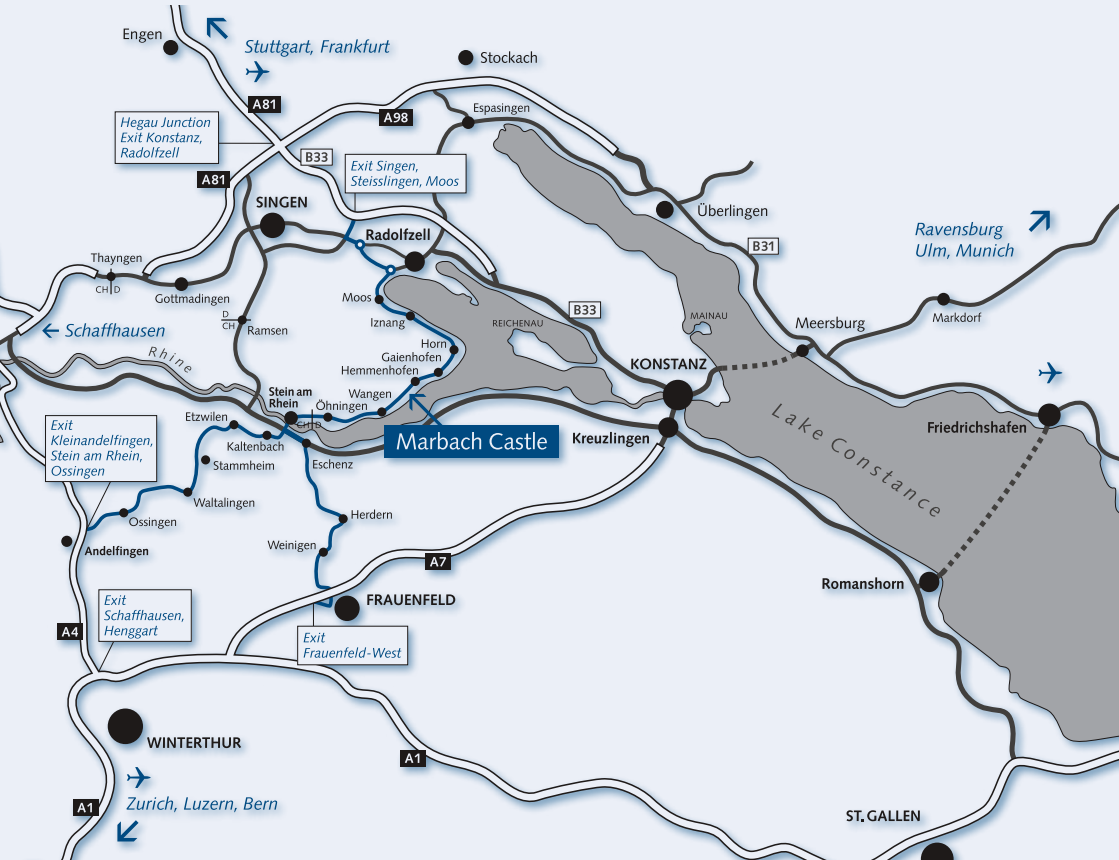
Marbach Castle is within easy reach of the major cities in the area (Zurich, Basel, Stuttgart,). The distance to Zurich International Airport is about 60 kilometres. Taxi from and to the Airport is approx. 90 Euros. An hourly airport shuttle for Workshop attendees will be organized at the arrival day. If driving, please find detailed itinerary descriptions posted under the Contact/Travelling item of the Marbach Castle web site.

REGISTRATION INFORMATION

Date, Time and Venue

Date	Workshop May, 26th to 28th, 2013
Venue	Marbach Castle +49 (0)7735 – 8130 D-78337 Öhningen info@schlossmarbach.de
Times	May 26th 2013 Afternoon: individual arrival, come together activity, come together dinner May 27th 2013 Start 09:00 a.m. – End 06:00 p.m. May 28th 2013 Start 08:30 a.m. – End 05:00 p.m.
Registration & Coffee	May 26th 2013 03:00 p.m. May 27th 2013 08:00 a.m.

MAP



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Registration Form

Please print your details

Title First name

Family name

Position

Department

Company

Address

City Post Code

Country

Tel No. Fax No.

E-mail

Date Signature

You may register by:

Mail: cr.appliance
Rossittenstraße 15
D-78315 Radolfzell
Fax: +49 (0)7732-820 953
Internet: www.cr-appliance.com
E-mail: karen.grave-hermann@cr-appliance.com

For further information please contact Karen Grave-Hermann
Phone: +49 (0)7732-820 951

Cancellation Policy

- Over 30 days prior to the Seminar: Cancellation fee of 200,00 €.
- 14 – 29 days prior to the Seminar: 50 % of the fee.
- Fewer than 14 days or if no notification received: Registrant liable to pay FULL seminar fee.

NB: Cancellation must be addressed in writing to karen.grave-hermann@cr-appliance.com

In the event circumstances beyond control, cr.appliance reserves the right to alter the programme, the speakers, the date or the venue.

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Workshop Fee (incl. Lunch, Dinner & Coffee Breaks, incl. 19 % VAT)

Please tick

Participation from May 26th to 28th, 2013	1.830,00 €	☐
Participation from May 26th to 28th, 2013, (members of ACCP, DMDG, DGRA or BioLago)	1.730,00 €	☐
Participation on May 27th and 28th, 2013 only	1.730,00 €	☐
Participation on May 27th and 28th, 2013 only, (members of ACCP, DMDG, DGRA or BioLago)	1.630,00 €	☐

Accommodation (incl. Breakfast and 19 % VAT)

A limited number of bedrooms are available at Marbach Castle (further Hotel capacities in close proximity available upon request):		1 night	2 nights
Category A:	single room (175,00 € per night)	☐	☐ (= 350 €)
	double room (225,00 € per night)	☐	☐ (= 450 €)
Category B:	single room (124,00 € per night)	☐	☐ (= 248 €)
	double room (174,00 € per night)	☐	☐ (= 348 €)
No hotel accommodation required:			☐

Application to Register

To ensure the personal workshop character of the event and provide maximum knowledge transfer benefits for the attendees, the overall number of participants is limited. Workshop participation will be assigned in the sequence of receipt of registration applications. Full confirmation of registration will occur by receipt of the Workshop fees.

Discounted Rates

Discounted rates may be granted for a limited number of participants on individual application for students, personnel from non-profit organizations and registered charities.