

**Hybrid format enabling
virtual attendance!**

SECOND ANNOUNCEMENT

14th International Workshop on Regulatory
Requirements and Current Scientific Aspects
of the Preclinical and Clinical Investigation of
Drug-Drug Interactions

Why You Should Attend

- **To know how we ended up caring about transporter mediated DDI** and the role that such assessment plays in current regulatory submissions,
 - **To become familiar with the role of PBPK in assessing transporter mediated DDI** and best practices involved in such modelling,
 - **To build up on your knowledge of endogenous biomarkers for transporter mediated DDI** that may help you avoiding a full blown dedicated clinical study using exogenous probes,
 - **To understand the interplay between protein binding and transporter uptake** in health and disease,
 - **To see the latest applications of Real-World Data Analysis** as applied to assessing the various DDI questions particularly during post-marketing commitments,
 - **To update yourself on scientific and practical aspects of DDI beyond what happens in average patient** and particular implications in paediatrics and geriatrics,
 - **To hear the debate about the clinical concerns over polypharmacy during pharmacotherapy in elderly** and whether we are too worried unjustifiably or there is a real issue,
 - **To reflect on practical issues that leads to failure of using PBPK for assessing DDI** and experts' views on how to avoid these,
 - **To expand your understanding of the DDI between biologics and small molecules** and what are the implications of latest guidance on practices during drug development
- ... and most importantly,
- **To network with a unique group of key opinion leaders from around the world** on all issues related to DDI, from scientific angles related to assessment to practical applications in drug development, and clinical practice.



Image: Marbach Castle Conference Center

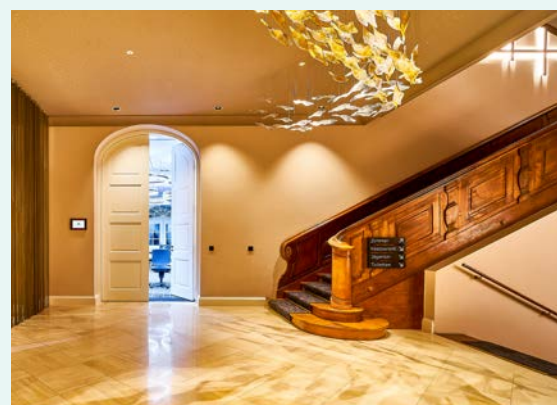
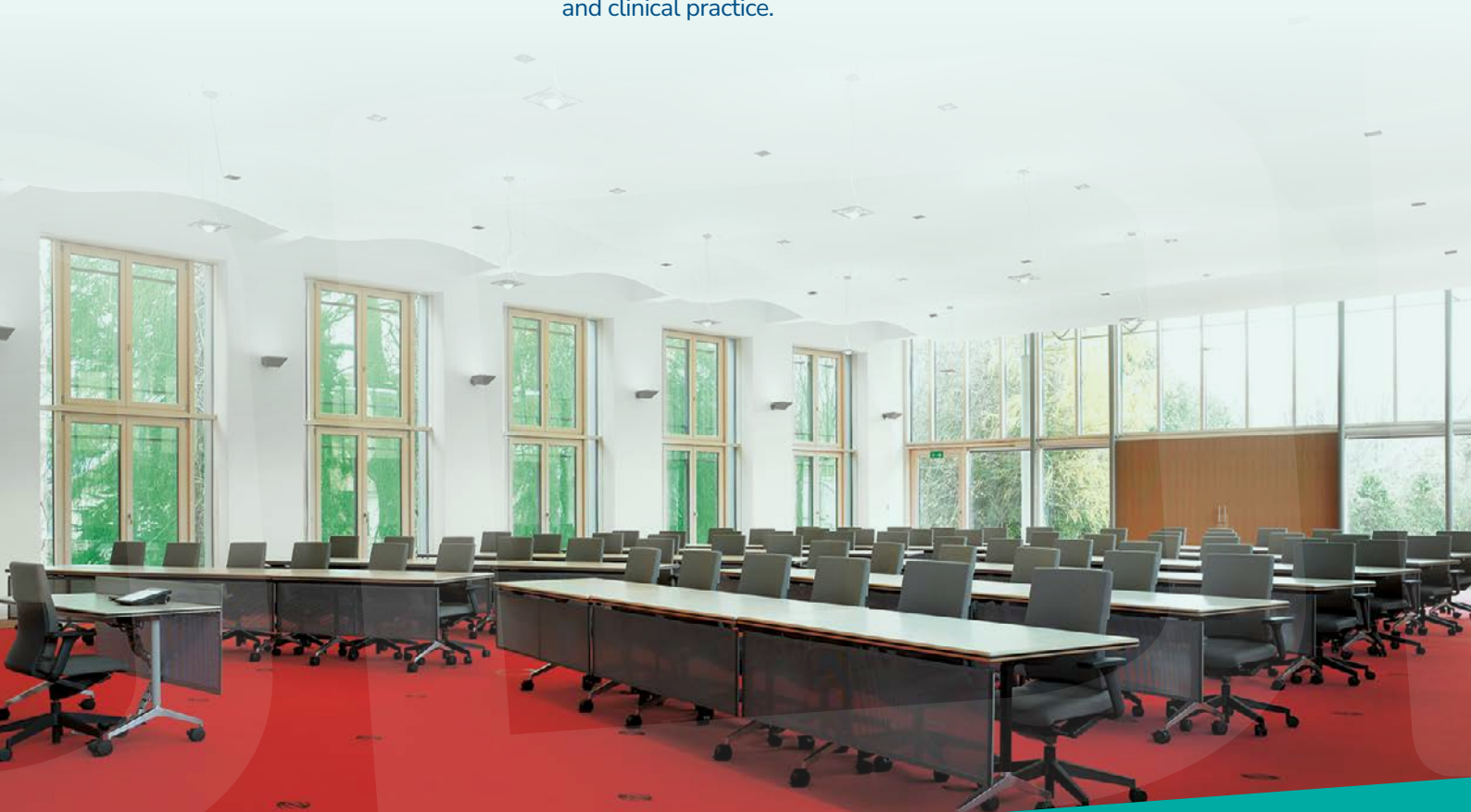


Image: Marbach Castle Conference Center



Mission Statement

The DDI workshop series is a non-profit programme to exchange research-based knowledge on drug-drug interactions (DDIs) among all interested stakeholders from pharmaceutical industry, regulatory authorities, academic and health care delivery backgrounds and perspectives.

The overall objective of the International Marbach Castle DDI Workshop series is to disseminate the scientific knowledge about drug-drug interactions (incl. food-drug and herb-drug interactions), and to foster communication for efficient preclinical and clinical investigation of DDIs.

The goal is continuous improvement of the safe use of drugs in the light of increasing poly-pharmacotherapy in particular in ageing and multi-morbid populations.

Background, Scope and Aim

In June 2010, the International Workshop on Regulatory Requirements and Current Scientific Aspects on the Preclinical and Clinical Investigation of DDIs was held for the first time. The workshop was based on an initiative of experts in the field from academia, consultancy, software and pharmaceutical industry, intrigued by the notion that the field of DDIs is getting increasingly important and complex in view of continuously emerging new therapies, new drug combinations, complex treatment algorithms for many widespread diseases and ageing populations. These factors converge into poly-pharmacotherapy with an increasing risk of clinically significant DDIs. Therefore, the early recognition, meticulous clinical investigation, and informative labelling 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 (i.e. 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. More details on the Workshop history have been published recently:

Derendorf H, von Richter O, Hermann R, Rostami-Hodjegan A. Drug-Drug Interactions: Progress Over the Past Decade and Looking Ahead to the Future. *Clin Pharmacol Ther.* 2019; 105:1289-1291.

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 associated 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 DDIs, transporter based DDIs, DDIs involving therapeutic proteins, tools extrapolating in vitro results to predict clinical outcomes in vivo (IVIVE) as well as information technology guiding the detection and management of DDIs have gained more importance over recent years. Furthermore, pharmacodynamic DDIs have gained increasing interest given the steady increase in drug combinations in clinical development.

Since its inception in 2010, the International Marbach Castle DDI Workshop has been designed to comprise all of the elements above, to foster discussions and exchanges of views for providing a holistic perspective on the complex field of drug-drug interactions.

Robert Hermann MD, FCP
Amin Rostami-Hodjegan, PhD, FCP
Ping Zhao, PhD



The Workshop Programme 2024

In its 14th year, the Marbach Workshop remains a forum that offers comprehensive coverage of various important and timely topics related to drug-drug interactions (DDIs).

The 2024 Workshop will open with a session on the latest science on transporter-based drug-drug interactions. This session will be initiated by a regulatory keynote address on Prudent Assessment of Transporter-Based DDIs. This will be followed by 3 presentations on various aspects of the role of endogenous biomarkers in the assessment of transporter-mediated drug-drug interactions.

In the second session, 3 presentations will revisit and expand the concepts and utility of real-world data analyses (RWDA) to evaluate DDIs. Complementing other quantitative methods, RWDA is increasingly used in drug development to inform safe and effective use of medicines. One presentation will introduce the audience into RWDA-tools to estimate the clinical and operational risks related to DDIs in clinical drug development. We hope the discussions around RWDA will bring attendees up to speed in realizing the strength, realities, challenges, and use cases of RWDA to manage clinical DDIs.

On Day 2 of the Workshop a session entitled “Too young or too old for drug-drug interactions?” will be featured to shed light on drug-drug interactions in special populations, with a particular focus on pediatric and elderly populations. A Q&A session as follow-on to the lectures in the previous session will offer the opportunity for in depth discussions of the multiple challenges in the DDI assessment in special populations.

The second session on Day 2 of the meeting will provide an update on DDIs with biologics including a review of the final 2023 FDA Guidance on Drug-Drug Interaction Assessment for Therapeutic Proteins.

A regulatory PBPK session will conclude Day 2 of the Workshop. The line-up of this session will consist of a “Point – Counter-Point” debate on the regulatory success of PBPK submissions. The first talk of this session will provide regulatory insights on “How to determine the adequacy of PBPK for assessing DDI as part of regulatory submissions?” with examples of common shortfalls. The subsequent counter-point presentation will focus on gaps and opportunities moving forward.

All sessions will provide plenty of opportunity for scientific and regulatory exchange and networking. Workshop participants can also submit abstracts for poster presentations throughout the Workshop.

As always, the topics of the 14th international DDI Workshop will be covered by distinguished international scientists, representatives from various national regulatory agencies, and experts from academia, pharmaceutical companies, contract research organizations as well.

The Workshop Organizers



Robert Hermann, MD, FCP



Amin Rostami-Hodjegan, PhD, FCP



Ping Zhao, PhD



Karen Grave-Hermann, MSc



Image: Marbach Castle Conference Center

Sunday, May 26th, 2024

Afternoon	Individual Arrival & Check-in at Marbach Castle
03:00 p.m.	Registration & Coffee
04:00 p.m.	Come Together Activities – TBD Poster Session – TBD
07:30 p.m.	Come Together Dinner

Monday, May 27th, 2024

08:00 – 09:00 a.m.	Registration & Coffee
09:00 – 09:15 a.m.	Welcome Address and Introduction into the Workshop <i>Ping Zhao</i>
Session I	Latest Science on Transporter-Based Drug-Drug Interactions <i>Chair: Amin Rostami</i>
09:15 – 09:50 a.m.	Keynote Lecture on Prudent Assessment of Transporter-Based DDIs <i>Shiew Mei Huang, PhD; Silver Spring, MD, USA</i>
09:50 – 10:00 a.m.	<i>Discussion</i>
10:00 – 10:30 a.m.	Use of Endogenous Biomarkers for Predicting Transporter-Mediated Drug Interactions Quantitatively; The Importance of Using PBPK Modeling <i>Yuichi Sugiyama, PhD; Innovation Base, Josai International University (JIU), Tokyo, Japan</i>
10:30 – 10:40 a.m.	<i>Discussion</i>
10:40 – 11:10 a.m.	A Metabolomic Analysis of Sensitivity and Specificity of Biomarkers for Renal Transporter-Mediated Drug-Drug Interactions <i>Arne Gessner, PhD; Institute for Clinical and Experimental Pharmacology and Toxicology, Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany</i>
11:10 – 11:20 a.m.	<i>Discussion</i>
11:20 – 11:50 a.m.	Networking Over Coffee Break
11:50 – 12:20 p.m.	Modelling Endogenous Biomarkers of Renal OAT1/3 to Assess Transporter-Mediated DDI in Healthy and Patients with Chronic Kidney Disease <i>Shawn Pei Feng Tan, PhD Student; Centre of Applied Pharmacokinetics Research, University of Manchester, UK</i>
12:20 – 12:30 p.m.	<i>Discussion</i>
12:30 – 02:00 p.m.	Networking Over Lunch

Monday, May 27th, 2024 (continued)

Session II	Real World Data on Drug-Drug Interactions <i>Chair: Ping Zhao</i>
02:00 – 02:30 p.m.	There and Back Again ... A Journey to Predict a Complex DDI and Confirm in the Real World – Implications for Drug Lifecycle Management <i>Grillo, Joseph A., PharmD; Winchester, VA, USA</i>
02:30 – 02:40 p.m.	Discussion
02:40 – 03:10 p.m.	Empowering Translational Research Through Transdisciplinary Data Integration <i>Stephan Schmidt, PhD, FCP; CPSP, University of Florida, Orlando, USA</i>
03:10 – 03:20 p.m.	Discussion
03:20 – 03:50 p.m.	Networking Over Coffee Break
03:50 – 04:20 p.m.	Real World Data Tools to Estimate the Clinical and Operational Risk Related to DDIs <i>Sebastian Haertter, PhD; Boehringer Ingelheim Pharma GmbH, Germany</i>
04:20 – 04:30 p.m.	Discussion
04:30 – 05:30 p.m.	Short Presentation of Selected Posters
05:30 – 05:45 p.m.	Q&A and Discussions on Transporter-Based DDIs and RWD
07:30 p.m.	Networking Over Dinner

Tuesday, May 28th, 2024

Session III	Too Young or Too Old for Drug-Drug Interactions? <i>Chair: Robert Hermann</i>
08:30 – 09:00 a.m.	DDI in Special Populations – Drug Development Implications in Industry and Case Example Based on Experience at Roche <i>Michael Gertz, PharmD, PhD; Translational PK/PD and Clinical Pharmacology (TPCP), pRED, Roche Innovation Center Basel, Switzerland</i>
09:00 – 09:10 a.m.	Discussion
09:10 – 09:30 a.m.	Opening Remarks – Pharmacotherapy in the Elderly <i>Petra A. Thürmann MD, PhD; Helios University Hospital Wuppertal; University Witten/Herdecke, Germany</i>
09:30 – 09:40 a.m.	Discussion
09:40 – 10:10 a.m.	Using Real World Data to Assess Drug-Drug Interactions under Multiple Drug Therapy: Focusing on Antibiotics in Elderly <i>Tjeerd Pieter van Staa, MD, PhD, MSc; Division of Informatics, Imaging & Data Sciences (L5), Centre for Health Informatics, University of Manchester, Manchester, UK</i>
10:10 – 10:20 a.m.	Discussion
10:20 – 10:50 a.m.	Networking Over Coffee Break

Tuesday, May 28th, 2024 (continued)

Session III	Too Young or Too Old for Drug-Drug Interactions? (ctd) <i>Chair: Robert Hermann</i>
10:50 – 11:20 a.m.	Drug-drug Interactions Coming-of-Age – The Challenge of Deciphering DDIs as Cause of Adverse Drug Reactions in Elderly Patients Undergoing Polypharmacy <i>Julia Stingl, MD; Institute of Clinical Pharmacology, University Clinic of the University of Aachen (RWTH Aachen)</i>
11:20 – 11:30 a.m.	Discussion
11:30 – 12:00 p.m.	Q&A and Discussions on DDIs in Special Populations
12:30 – 02:00 p.m.	Networking Over Lunch
Session IV	Drug-Drug Interactions with Biologics Revisited <i>Chair: Amin Rostami</i>
02:00 – 02:30 p.m.	Update on DDIs with Biologics and Review of Final FDA Guidance on Drug-Drug Interaction Assessment for Therapeutic Proteins <i>Bernd Meibohm, PhD, FCP; College of Pharmacy, University of Tennessee Health Science Center, Memphis, USA</i>
02:00 – 02:40 p.m.	Discussion
Session V	Point – Counter-Point: Regulatory – Success of PBPK Submissions <i>Chair: Ping Zhao</i>
02:40 – 03:05 p.m.	Point – How to Determine Adequacy of PBPK for Assessing DDI as Part of General Assessment? The Common Shortfalls. <i>Yuching Yang, PhD; Durham, North Carolina, USA</i>
03:05 – 03:10 p.m.	Discussion
03:10 – 03:35 p.m.	Counter Point – How to Determine Adequacy of PBPK for Assessing DDI as part of Regulatory Submissions? Addressing the Gaps and Filling the Void <i>Eva Gil Berglund, PhD; Clinical Pharmacology and Regulatory Strategy, CDDS, Certara, NL</i>
03:35 – 03:40 p.m.	Discussion
03:40 – 04:00 p.m.	Networking Over Coffee Break
04:00 – 04:20 p.m.	Q&A and Discussions on DDIs in Special Populations
04:20 – 04:30 p.m.	Concluding Remarks – Amin Rostami End of Meeting & 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: <http://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 (ZRH) is about 60 kilometres.

Ground Transport from Zurich Int. Airport to Marbach Castle

Because of the increasing unreliability and unpunctuality of flight traffic as a consequence of the Covid-19 pandemic, it has turned out that organisation of taxi shuttles is unfortunately no longer practically feasible under these circumstances.

As most suitable and flexible option it is therefore recommended to using the train from Zurich Airport to either Singen am Hohentwiel or Radolfzell am Bodensee (one train change in Winterthur).

There are a total of 85 connections per day from Zurich Airport to Singen am Hohentwiel. The train departs in Zurich every 10 minutes and the connecting train in Winterthur every 40 minutes; the shortest

travel time to Singen is 55 minutes the travel time to Radolfzell about 10 minutes longer. The average travel time is about 1.3 hours; ticket prices may range between 20 to 34€.

The distance from the station in Singen am Hohentwiel to Marbach Castle is about 21 km, travel time by taxi is about 25 minutes.

The distance from the station in Radolfzell am Bodensee to Marbach Castle is about 20 km, travel time by taxi is about 20 minutes. Alternatively, a bus can be taken from the train station Radolfzell to Marbach Castle. The bus leaves every 30 minutes and travel time is about 30 minutes.

Prices for a Swiss taxi from Zurich Int. Airport to Marbach Castle may range between 150 to 250 CHF, travel time is about 1 hour (63 km). Alternatively one may consider using a rental car from the airport.

Poster Presentations

As always, there will be an opportunity for Workshop participants to submit abstracts for poster presentations throughout the Workshop.



Image: Marbach Castle Conference Center

Date, Time and Venue

Date	Workshop May, 26th to 28th, 2024	
Venue	Marbach Castle, D-78337 Öhningen +49 (0)7735 – 8130, info@schlossmarbach.de	
Times	May 26th 2024 Afternoon Individual arrival, come together, come together activity, come together dinner, Poster Session, Social Event (Details to be Determined)	
	Scientific Programme	
	May 27 th 2024	Start 09.00 a.m. – Finish 05.00 p.m.
	May 28 th 2024	Start 08.30 a.m. – Finish 04.30 p.m.
Registration & Coffee	May 26 th 2024	03.00 p.m.
	May 27 th 2024	08.00 a.m.

Register Online for Workshop and News Feed
www.ddi-workshop-marbach.org

Registration

Considering the still ongoing uncertainties around the course of the Covid-19 pandemic, we are planning for a “hybrid” meeting. Also for the 2024 Workshop this means that speakers and attendees will have the opportunity to opt by certain date (see below) between attendance in person at Marbach Castle or for a virtual attendance via video conference (Zooms).

There are several factors which are beyond our control. These include rules and requirements of local authorities on size of the gatherings for meetings, as well as international and company guidelines governing travel. In case that any of such restrictions will still be in place by end of May, thereby precluding a gathering of a meaningful number of attendees at Marbach Castle, the entire Workshop will be held as a virtual meeting.

Registration for Physical Attendance at Marbach Castle

Keeping with the tradition of the Marbach event in the past, to maintain the tradition of Marbach DDI Workshop that assures optimal scientific exchange and interaction at personal level, we limit the number of participants to about 70. Therefore, early registration is recommended, to assure your place at the Workshop. In case the meeting is fully booked, a “standby” registration option will be considered which may come into effect in case of cancellations.

Registration for Virtual Conference Attendance

Because of the ongoing Covid-19 pandemic, registration for a web-based virtual conference attendance on May 27th and May 28th, is possible for the Workshop 2024. Only 2-day registrations for the entire event will be accepted. The fees for the virtual conference attendance

will be about 50% of the fees applicable for the physical 2-day attendance at Marbach Castle. The number of virtual conference attendees is limited to 100.

Registration Formalities and Procedures

Workshop participation will be assigned in the sequence of receipt of registration applications. Full confirmation of registration, however, will only be granted upon complete receipt of the Workshop fees, which become payable within 3 weeks after submission of the registration application.

You may register via the Workshop Secretary by:

- ✉ E-Mail: secretary@ddi-workshop-marbach.org
- ✉ Fax: +49(0)6051-97 166 93

or by using the registration form below.

Registration Form

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

3-Day Participation from May 26 th to May 28 th , 2024	2.250,00 €	<input type="checkbox"/>
3-Day Participation from May 26 th to May 28 th , 2024, (for members of ACCP or DMDG)	2.150,00 €	<input type="checkbox"/>
2-Day Participation on May 27 th and May 28 th , 2024 only	2.150,00 €	<input type="checkbox"/>
2-Day Participation on May 27 th and May 28 th , 2024 only, (in combination with discounted rate for members of ACCP or DMDG)	2.050,00 €	<input type="checkbox"/>
2-Day Participation Virtual Conference on May 27 th May June 28 th , 2024	1.250,00 €	<input type="checkbox"/>

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 (230,00 € per night)	<input type="checkbox"/>	<input type="checkbox"/>
double room (310,00 € per night)	<input type="checkbox"/>	<input type="checkbox"/>
Category B: single room (149,00 € per night)	<input type="checkbox"/>	<input type="checkbox"/>
double room (229,00 € per night)	<input type="checkbox"/>	<input type="checkbox"/>
No hotel accommodation required:		<input type="checkbox"/>

You may register by

Internet

www.ddi-workshop-marbach.org

E-mail

secretary@ddi-workshop-marbach.org

Fax

+49(0)6051-97 166 93

For further information please contact Karen Grave-Hermann.

E-mail: secretary@ddi-workshop-marbach.org

Phone: +49(0)6051-97 166 91

Cancellation Policy

- More than 60 days prior to the Workshop: Cancellation fee of 200,00 €.
- Within 31 – 59 days prior to the Workshop: 50 % of the fee.
- Less than 30 days or if no notification received: Registrant liable to pay FULL Workshop fee.

Please print your details

Salutation (Mr/Ms)	City
Title	Postal Code
First name	Country
Family name	Phone
Position	Fax
Department	E-Mail
Company	Date
Address	Signature

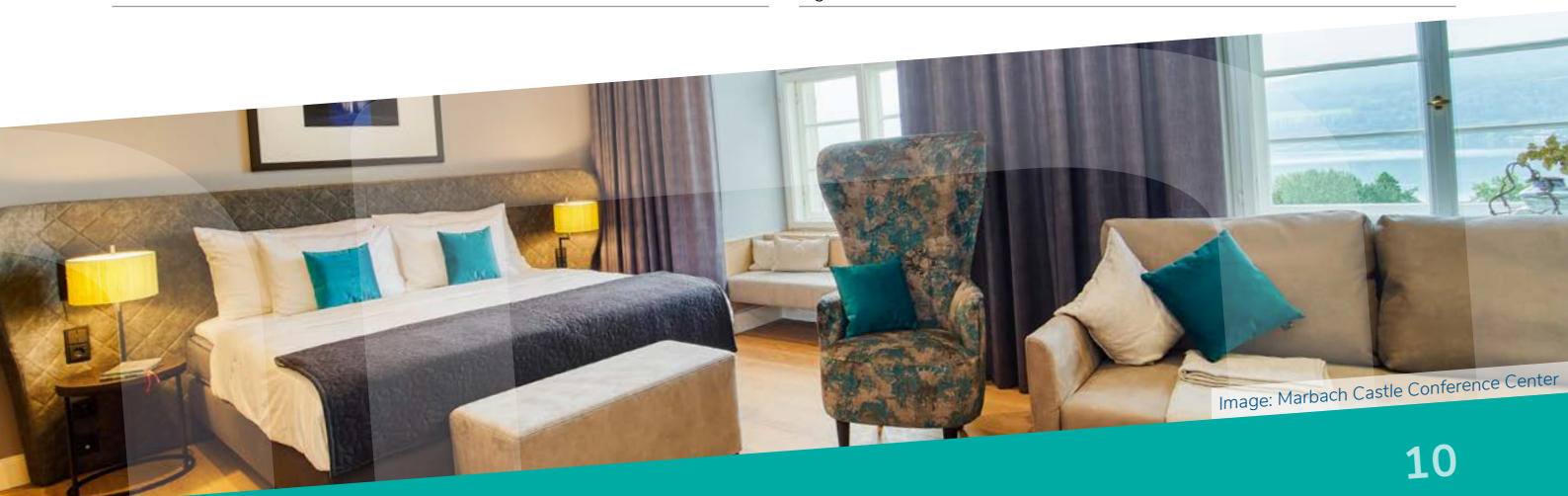


Image: Marbach Castle Conference Center

European Protection Law (EDPL)

By filling out the registration form, the participant gives consent to the DDI Workshop Faculty to process the data provided within the framework of the conference and in compliance with the EDPL Legislation. This includes the following, unless registered participants object:

- All personal details needed for the applicant's participation at the event - invoicing, participant list, Certificate of Attendance, contact about the registration, specific diet information, etc
- Pictures taken during the conference:
 - Accessible only by participants (PW-protected Website)
 - Accessible by Website visitors (public Website area)

Data collection and processing: Personal Data and Contact Information will be exclusively used within the framework of registration to the aforementioned event and will not be shared publicly. The collected data is stored on a secured server.

Right of access: applicants have a right to access and ask for changing or deleting their personal data and pictures.

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 on the Workshop fee of 100 € will be granted for members of ACCP or DMDG. In addition, a limited number of participants may receive discounted fees based on individual applications of students, personnel from non-profit organizations and registered charities.

Cancellation

Note: Cancellation must be addressed in writing to (e-mail sufficient) to the Workshop Secretary: secretary@ddi-workshop-marbach.org

In the event of circumstances beyond control, the Workshop Organizers reserve the right to alter the programme, the speakers the date or the venue.



Marbach Map

