DDI 2022
Marbach DDI Workshop

May 29th to 31st, 2022
Marbach Castle, Germany

Hybrid format enabling virtual attendance!

Programme includes ICH M12 (DDI) update

12th International Workshop on Regulatory Requirements and Current Scientific Aspects of the Preclinical and Clinical Investigation of Drug-Drug Interactions

ACCP American College of Clinical Pharmacology
DM DG Drug Metabolism discussion group
BioLAGO life science network

VERY FINAL ANNOUNCEMENT

Why You Should Attend

- **Build up knowledge** on regulatory expectations in China and DDI guidance of NMPA
- **Evaluate potential** impact of the harmonisation between regulatory agencies on DDI through ICH
- **Become familiar** with the concept of real-world data gathering and analysis
- **Learn how to utilize** real-world data to evaluate DDIs with example case of contraceptives
- **Compare and Contrast** regulatory views on the applications of real-world data for assessing DDI
- **Get informed** of the varying impact on label language that each DDI assessment strategy provides (RWDA, PBPK, Clinical Assessment)
- **Revisit the complex DDI** and approaches to deal with them during drug development
- **Understand the impact** that COVID-19 had on conduct of DDI studies
- **Know requirements** for rapid application of PBPK approach to asses DDI in the COVID-19 era
- **Hear about the latest update** on DDI assessment for biologics
- **Go beyond average** and appreciate the gene-drug-drug interactions
- **Delve into PPI-related DDI** and the latest guidance on how to assess them
- **Uncover the mechanisms** behind rare DDI's caused by changes in GI tract physiology

... and most importantly meet, discuss and network with a unique selection of scientific and regulatory experts from pharmaceutical and contract research-industries, international regulatory bodies, non-government organizations and academia.

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 multimorbid 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.

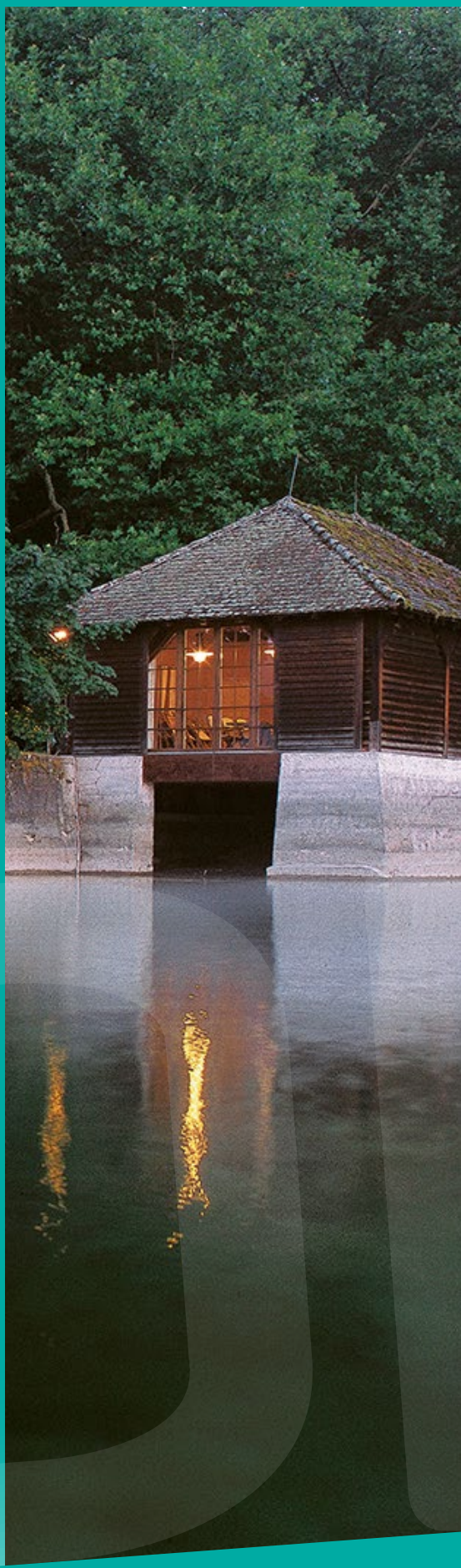
Failures in the early recognition, mechanistic elucidation (i.e. understanding) and proper clinical management of DDIs, in turn, have resulted in numerous drug withdrawals from the market in the past and continue to result in a significant health burden to patients as well as an economic burden on healthcare 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 2022

The 2022 Workshop will open with a keynote lecture on 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. The keynote lecture will be immediately followed by a session on applying RWDA to assess DDI risks. We hope the discussions around RWDA will bring attendees up to speed in realizing the strength, realities, and use cases of RWDA to manage clinical DDIs.

The next "regulatory session" follows workshop's tradition. International Council for Harmonization (ICH) decided to publish its first DDI guideline M12. Attendees will hear updates from global regulators on respective DDI requirements. A panel discussion is designed to bring together thoughts towards global harmonization.

After the regulatory session there will be a panel discussion on the utility of dosing apps that are based on in silico models. In a digital world that we live in today, a mobile or computer app helping physicians to make timely decisions on optimal dosing considering a patient's potential complex co-medication seems highly desirable. We will hear perspectives from app developers on current features and challenges.

Day 2 of the workshop will begin with the session on "Conduct of DDI under the COVID-19 pandemic". The ability to conduct in-silico trials using existing virtual physiology models and to investigate plausible pharmacology using mechanistic models have made impact on decisions at many levels of drug R&D and clinical use since the beginning of the COVID-19 pandemics. Attendees will hear cases in the area of drug repurposing as well as acceleration of the development and registration of investigational drugs.

The COVID-19 DDI session will then be followed by a session on the role of pharmacogenetics in DDI, and a talk on DDI assessment for therapeutic proteins. The following session will be dedicated to absorption DDIs, and will comprise two presentations: The first being an IQC update on pH-Dependent DDIs and food effects, while the second will be about absorption DDIs by drugs affecting GI-tract motility.

The last session is a new format called "Marbach Debate". We will select one of the several hot topics in 2021 based on Q&As and panel discussions and invite perspectives from industry, academic, and regulators.

As situations on travel restrictions continue to improve, we are hoping to welcome you in the newly renovated facilities at Marbach in May of 2022!

The Workshop Organizers

Robert Hermann, MD, FCP

Amin Rostami-Hodjegan, PhD, FCP

Ping Zhao, PhD

Workshop Programme

Sunday, May 29th, 2022	
Afternoon	**Individual Arrival & Check-in at Marbach Castle**
03:00 p.m.	**Registration & Coffee**
04:00 p.m.	**Come Together Activities**
07:30 p.m.	**Come Together Dinner**
09:00 p.m.	**Social Event – Details to be Determined**

Monday, May 30th, 2022	
08:00 – 08:30 a.m.	**Registration & Coffee**
08:30 – 08:45 a.m.	**Welcome Address and Introduction into the Workshop** *Amin Rostami*
	Keynote Lecture
08:45 – 09:20 a.m.	**Concepts and Utility of Real-World Data Analyses to Evaluate DDIs** *Douglas McNair, MD/PhD, BMGF, USA*
09:20 – 09:30 a.m.	*Discussion*
Session I	**Real-World DDI Evidence** *Chair: Ping Zhao*
09:30 – 09:50 a.m.	**Understanding Contraceptive DDIs through Combining Pharmacology Models and RWDA** *Stephan Schmidt, PhD, University of Florida, Gainesville, USA.*
09:50 – 10:00 a.m.	*Discussion*
10:00 – 10:30 a.m.	**Coffee Break**
10:30 – 10:50 a.m.	**DDI Labelling: Can RWE Complement Regulatory Decisions on DDI Management in Product Labels?** *Joseph A. Grillo, PharmD, Winchester, VA, USA*
10:50 – 11:00 a.m.	*Discussion*
11:00 – 11:20 a.m.	**Utility of Clinical Practice Research Datalink (CPRD) to Evaluate Drug-Drug Interactions and DDI in Special Populations** *Justin Hay, PhD, Certara, UK*
11:20 – 11:30 a.m.	*Discussion*
11:30 – 12:00 p.m.	**Panel Discussions and Q&A on RWD – DDIs**
12:00 – 01:30 p.m.	**Lunch**

Workshop Programme

Monday, May 30th, 2022 *(continued)*	
Session II	**Roadmap to ICH-M12** *Chair: Robert Hermann*
01:30 – 02:00 p.m.	**Highlight of DDI Guideline of Chinese NMPA** *Li Li, PhD, National Medical Products Administration, China*
02:00 – 02:10 p.m.	*Discussion*
02:10 – 02:40 p.m.	**EMA DDI Guideline and ICH M12** *Carolien Versantvoort, PhD, Medicines Evaluation Board, The Netherlands*
02:40 – 02:50 p.m.	*Discussion*
02:50 – 03:20 p.m.	**Regulatory Panel Discussions and Q & A for Session II**
03:20 – 04:00 p.m.	**Coffee Break**
Session III	**Usefulness of PBPK Modelling to Address Complex / Network PK Interactions** *Chairs: Rodrigo Cristofoletti (University of Florida), Ping Zhao and Amin Rostami-Hodjegan*
04:00 – 05:00 p.m.	**Panel Discussion on Complex/Network PK DDIs**
05:00 – 05:15 p.m.	**Planning of a European Professional Development Curriculum for the Comprehensive Assessment of Drug-Drug Interactions** *Béatrice Saint-Salvi, PhD, DDI Unit, ANSM, France*
05:15 – 05:20 p.m.	*Discussion*
07:00 p.m.	**Dinner**

Tuesday, May 31st, 2022	
Session IV	**COVID-19 & Conduct of DDI** *Chair: Amin Rostami-Hodjegan*
09:00 – 09:20 a.m.	**Informing Dosing Decisions Early in Pandemics** *Dongyang Liu, PhD, Peking University, Third Hospital, Beijing, China*
09:20 – 09:30 a.m.	*Discussion*
09:30 – 09:50 a.m.	**Remdesivir Approval Supported by Mechanistic Modelling** *Ramesh Palaparthy, PhD, Gilead Sciences, South San Francisco, CA, USA*
09:50 – 10:00 a.m.	*Discussion*
10:00 – 10:20 a.m.	**PBPK Modelling to Support DDI Assessment for Regulatory Submissions – General Observations during the COVID Era** *Hannah Jones, PhD, Certara, UK*
10:20 – 10:30 a.m.	*Discussion*
10:30 – 11:10 a.m.	**Coffee Break**

Tuesday, May 31st, 2022 (continued)	
Session V	**Pharmacogenetics** *Chair: Ingolf Cascorbi*
11:10 – 11:30 a.m.	**Drug-Drug-Gene Interactions** *Henrike Bruckmüller, PhD, Institute of Experimental and Clinical Pharmacology, University Hospital Schleswig-Holstein, Kiel, Germany; University of Tromsø, The Arctic University of Norway, Norway*
11:30 – 11:40 a.m.	*Discussion*
Session VI	**Biologics DDIs** *Chair: Amin Rostami-Hodjegan*
11:40 – 12:00 p.m.	**Assessing Therapeutic Peptide DDIs During Drug Development** *Carolina Säll, PhD, Novo Nordisk, Denmark*
12:00 – 12:10 p.m.	*Discussion*
12:10 – 01:40 p.m.	**Lunch**
Session VII	**Gut DDI** *Chair: Ping Zhao*
01:40 – 02:00 p.m.	**Physiology Based Biopharmaceutics Modeling (PBBM) based food effect predictions: Current state and future perspectives** *Christian Wagner, PharmD/PhD, Merck KGaA*
02:00 – 02:10 p.m.	*Discussion*
02:10 – 02:30 p.m.	**Absorption DDIs by Drugs Affecting GI-Tract Motility – A Case Example of a Fixed Drug Combination Development** *Robert Hermann MD, FCP, cr.appliance, Gelnhausen, Germany*
02:30 – 02:40 p.m.	*Discussion*
02:40 – 03:00 p.m.	**Coffee Break**
03:00 – 04:00 p.m.	**Marbach Debate** *Question to be Updated Based on Hot Topics in 2021 Meeting*
10 min	**Reactions from Regulatory Attendees**
10 min	**Reactions from Industry/Academic Attendees**
40 min	**Discussions – All**
04:00 p.m.	**Concluding Remarks – Amin Rostami-Hodjegan** **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. Airport taxi shuttles for Workshop attendees will be organised on Sunday May 29th and Tuesday May 31st. Taxi from and to the Airport is approx. 120 €.

Alternatively, the train form Zurich Airport to Stein am Rhein (train change in Winterthur) can be used (train departs in Zurich every 10 minutes and the connecting train in Winterthur every 40 minutes; average travel time 1.5 hours; 20 to 30 €). In case of train travel the Congress Secretary needs to be informed about the travel schedule and arrival time in Stein am Rhein in order to organize a taxi shuttle from Stein am Rhein to Marbach Castle. Please find detailed itinerary descriptions posted under the Contact/Travelling item of the Marbach Castle web site, if you arrange the travel yourself.

Poster Presentations

Because of the "hybrid" format of the 2021 Workshop, this year no poster presentation will take place.

Registration Information

Date, Time and Venue	
Date	**Workshop May, 29th to May 31st, 2022**
Venue	**Marbach Castle, D-78337 Öhningen** +49 (0)7735 – 8130, info@schlossmarbach.de
Times	**May 29th 2022 Afternoon** Individual arrival, come together, come together activity, come together dinner, Social Event (Details to be Determined) **Scientific Programme** May 30th 2022 Start 08.30 a.m. – Finish 05.00 p.m. May 31st 2022 Start 09.00 a.m. – Finish 04.00 p.m.
Registration & Coffee	May 29th 2022 03.00 p.m. May 30th 2022 08.00 a.m.

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

Registration

Considering the current uncertainties around the course of the Covid-19 pandemic, including the spread of more infectious virus mutations on the one hand, and the progress of the vaccination programs across the world on the other hand, we are currently planning for a "hybrid" meeting this year. 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 30th and May 31st, is possible for the Workshop 2022. Only 2-day registrations for the entire event will be accepted. The fees for the virtual conference attendance will be 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

DDI 2022 Marbach DDI Workshop

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

3-Day Participation from May 29th to May 31st, 2022	1.960,00 €	☐
3-Day Participation from May 29th to May 31st, 2022, (for members of ACCP, DMDG or BioLago)	1.860,00 €	☐
2-Day Participation on May 30th and May 31st, 2022 only	1.860,00 €	☐
2-Day Participation on May 30th and May 31st, 2022 only, (in combination with discounted rate for members of ACCP, DMDG or BioLago)	1.760,00 €	☐
2-Day Participation Virtual Conference on May 30th and May 31st, 2022	930,00 €	☐

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 (198,00 € per night)*	☐	☐
	double room (278,00 € per night)	☐	☐
Category B:	*single room (134,00 € per night)*	☐	☐
	double room (214,00 € per night)	☐	☐
No hotel accommodation required:			☐

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

Please print your details

Salutation (Mr/Ms)

Title

First name

Family name

Position

Department

Company

Address

City

Postal Code

Country

Phone

Fax

E-Mail

Date

Signature

Registration Information

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

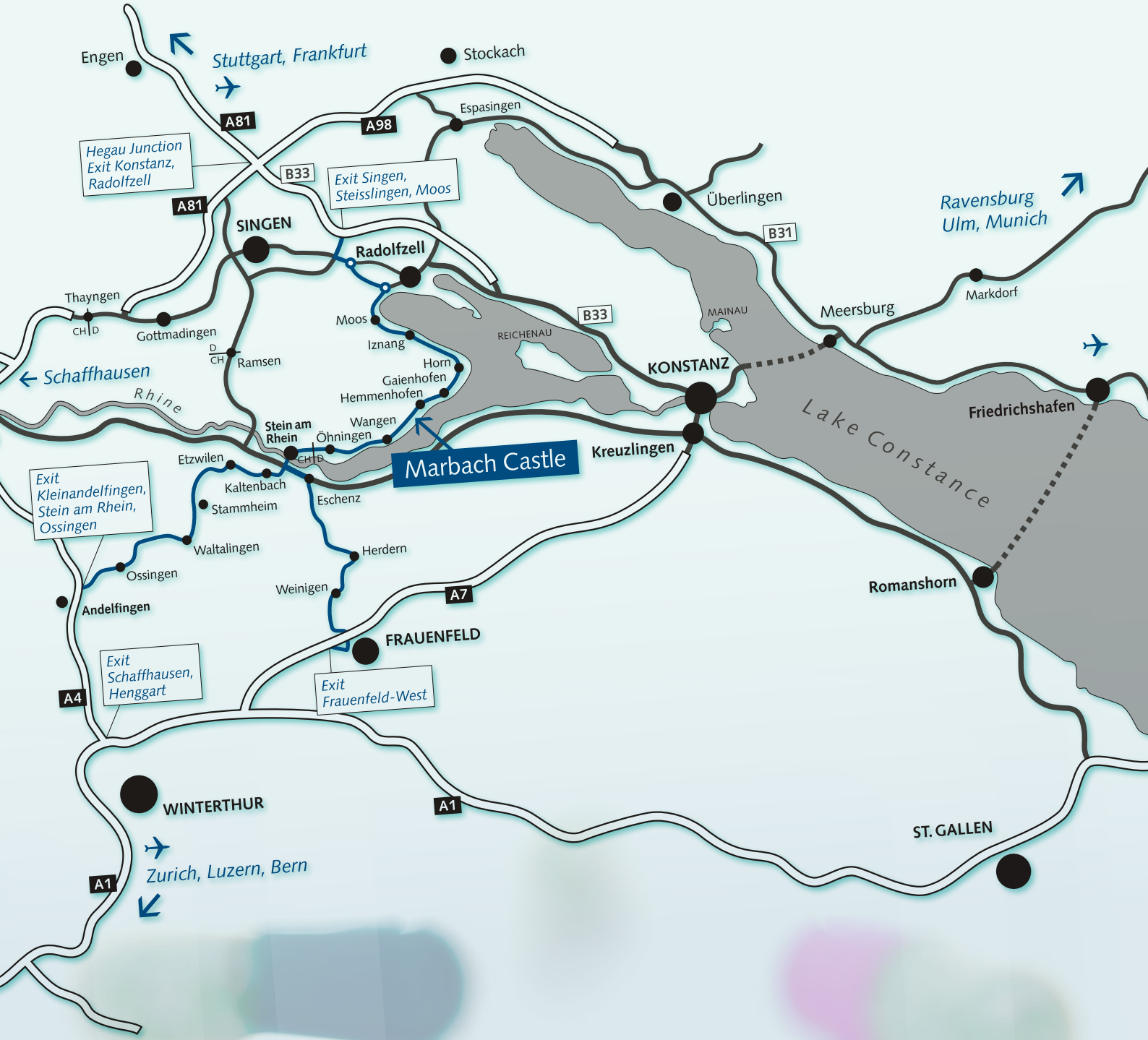
Discounted rates on the Workshop fee of 100 € will be granted will be granted for members of ACCP, DMDG or BioLago. In addition, a limited number of participants may receive discounted fees based on individual applications of students, personnel from non-profit organizations and registered charities.

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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