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THIRD ANNOUNCEMENT

16th International Workshop on Regulatory
Requirements and Current Scientific
Aspects of the Preclinical and Clinical
Investigation of Drug-Drug Interactions

Why You Should Attend

- **To Understand the Ins & Outs of Platform Qualification by EMA Report** in the Context of Use of DDI Prediction During Drug Development,
 - **To Know Implications of Predicting DDI** in Relation to Reducing FDA Post-marketing Requirements (PMR) and Commitments (PMC),
 - **To Become Familiar with the Pros and Cons of Relaxing Exclusion Criteria** During Phase III Studies in Relation to Potential DDI,
 - **To Build a More Comprehensive Knowledge of Links between the Patient Covariates** Such as Pharmacogenetics and Organ Function and the Level of DDI,
 - **To Update Yourself on DDI** Concerning Non-CYP Enzymatic Routes Such as UGTs,
 - **To Revisit Advantages vs Disadvantages of Using Ready-Made Platforms** for DDI Predictions as Part of Drug Development Process,
 - **To Take Part in Discussions Around Accelerating Translation and Transition** of Latest Science on DDI from Bench to Bedside for the Benefit of Patients,
- ... and most importantly,
- **To Network with a Unique Group of Key Opinion Leaders from Industry, Academia, Regulatory Agencies and CRO** Gathering from Around the World on Issues Related to Understanding and Managing DDIs during Drug Development and in the Clinic.



Image: Marbach Castle Conference Center

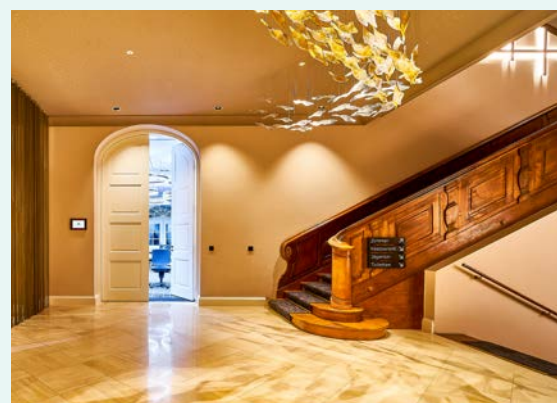


Image: Marbach Castle Conference Center



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 and advance 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 and rational 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. It was 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. Since 2010, the pace of drug development remained at a high level, with about 50 new molecular entities obtaining marketing approval each year, often with limited information on clinical DDIs.

Therefore, the early recognition, mechanistic understanding, 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, 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:

- 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 way, 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.

In 2025, Robert Hermann and Karen Grave-Hermann stepped back and transferred the responsibility to a partially renewed team. We thank Robert and Karen for their invaluable contribution to start and maintain the workshop series for so many years. We hope to continue welcoming them at the future meetings and will always try to be up to their legacy.

Uwe Fuhr, MD
Amin Rostami-Hodjegan, PhD, FCP
Ping Zhao, PhD
Isabelle Ragueneau-Majlessi, MD
Dr. Wafaâ Jabrane



The Workshop Programme 2026

In its 16th year, the Marbach Workshop brings together international experts to discuss current topics in drug-drug interactions. The 2026 event will update attendees on recent scientific advances and clinical applications.

The workshop starts Monday, June 1st, 2026, with Session I: DDI Implementation from Bench to Bedside. Presentations will cover challenges in applying research to clinical practice, especially for DDIs and pharmacogenomics. Academic and regulatory speakers will address knowledge gaps at drug approval, and industry experts will discuss personalized DDI management strategies.

Following a discussion at 2025 workshop with regard to publication of European Medicines Agency's (EMA) opinion report on qualifying PBPK platforms for DDI prediction, the 2026 workshop will dedicate a session (Session II) where experts from EMA, UK's MHRA, Certara, and J&J will reflect on review experience of regulator and software developer, and present stakeholders' feedback on the first-of-its-kind PBPK qualification report.

On Tuesday, June 2nd, Session III covers managing complex drug interactions in vulnerable groups, including case studies from the COVID-19 pandemic and strategies for geriatric and underserved patient groups.

Session IV focuses on advancements in in vitro assays for non-CYP induction, discussing UGT induction, PBPK extrapolation, and CYP3A / UGT co-induction in DDI prediction.

Each session during the event will include interactive discussions, and participants may submit abstracts for poster presentations in Session V: Poster Session. The workshop provides an opportunity for exchanging information and networking.

The Workshop Organizers:

Uwe Fuhr, MD

Amin Rostami-Hodjegan, PhD, FCP

Ping Zhao, PhD

Isabelle Ragueneau-Majlessi, MD

Dr. Wafaâ Jabrane



Uwe Fuhr, MD



Amin Rostami-Hodjegan, PhD, FCP



Ping Zhao, PhD



Isabelle Ragueneau-Majlessi, MD, MSc



Dr. Wafaâ Jabrane



Image: Marbach Castle Conference Center

Sunday, May 31st, 2026

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, June 1st, 2026

08:00 – 09:00 a.m.	Registration & Coffee
09:00 – 09:15 a.m.	Welcome Address and Introduction into the Workshop <i>Uwe Fuhr, Amin Rostami</i>
Session I	DDI Implementation from Bench to Bedside: Challenges and Opportunities <i>Chair: Isabelle Ragueneau-Majlessi</i>
09:15 – 10:00 a.m.	KEYNOTE LECTURE: What Are the Hurdles Delaying Transition of Science from Bench to Bedside: Lessons from Pharmacogenomics and Implications for the Case of Managing DDI <i>Sir Munir Pirmohamed, Professor, David Weatherall Chair of Medicine, University Liverpool, United Kingdom</i>
10:00 – 10:15 a.m.	<i>Discussion</i>
10:15 – 10:45 a.m.	Addressing Drug-Drug Interaction Knowledge Gaps During Drug Development with Modeling-Informed Approach: What We Can Learn from the Past <i>Xinning Yang, PhD, Clinical Pharmacologist, Ellicott City, Maryland, United States of America</i>
10:45 – 10:55 a.m.	<i>Discussion</i>
10:55 – 11:25 a.m.	Networking Over Coffee Break & Visiting Posters
11:25 – 11:55 a.m.	Implementing PGx and DDI Management Programs to Support Personalized Prescription: How to Successfully Translate Scientific Mechanistic Knowledge into Clinical Practice. <i>Houda Hachad, PharmD, M.Res., Vice President of Clinical Operations, Arancia, United States of America</i>
11:55 – 12:05 a.m.	<i>Discussion</i>
12:05 – 12:30 p.m.	Panel discussion
12:30 – 02:00 p.m.	Networking Over Lunch

Monday, June 1st, 2026 (continued)

Session II	The EMA PBPK Model Qualification Pathway <i>Chair: Amin Rostami</i>
02:00 – 02:30 p.m.	Model Qualification Pathway at EMA: The PBPK Case with DDI as Context of Use <i>Efthymios Manolis, PharmD, EMA, The Netherlands</i>
02:30 – 03:00 p.m.	Navigating EMA Qualification of a PBPK Platform: CYP-Mediated DDIs as the Context of Use <i>Karen Rowland Yeo, PhD, Certara, United Kingdom</i>
03:00 – 03:30 p.m.	Networking Over Coffee Break & Visiting Posters
03:30 – 03:40 p.m.	Feedback on EMA Qualification <i>Susan Cole, MHRA, United Kingdom</i>
03:40 – 03:50 p.m.	Feedback on EMA Qualification <i>Loeckie De Zwart, PhD, J&J, Belgium</i>
03:50 – 04:00 p.m.	Reflections on Qualification <i>Dr. Rolf Burghaus, PhD, Head Virtual Patients, Bayer AG, Germany</i>
04:00 – 04:10 p.m.	Feedback on EMA Qualification <i>Yuching Yang, Silver Spring, Washington DC, United States of America</i>
04:10 – 05:00 p.m.	Panel Discussion
07:00 p.m.	Networking Over Dinner

Tuesday, June 2nd, 2026

Session III	Complex DDIs <i>Chair: Uwe Fuhr</i>
08:30 – 09:15 a.m.	KEYNOTE LECTURE: Understanding Complex DDIs in COVID-19 Treatment: Advancing from Static to Dynamic Models and toward AI-Enabled Approaches <i>Eric Chan, Professor, National University of Singapore, Singapore</i>
09:15 – 09:30 a.m.	<i>Discussion</i>
09:30 – 09:55 a.m.	Novel Strategies for the Evaluation and Management of Drug-Drug Interactions in Geriatric Patients. <i>Zhu Zhou, PhD, Associate Professor, Dept. of Pharmaceutical Sciences, University of the Pacific, Stockton, United States of America</i>
09:55 – 10:05 a.m.	<i>Discussion</i>
10:05 – 10:30 a.m.	Networking Over Coffee Break & Visiting Posters
10:30 – 10:55 a.m.	An Integrated Approach to Enable Efficient Management of Complex DDIs in Global Health <i>Lisa Almond, PhD, Certara, United Kingdom</i>
10:55 – 11:05 a.m.	<i>Discussion</i>

Tuesday, June 2nd, 2026 (continued)

11:05 – 11:30 a.m.	PBPK in Antimalarial Drug Development – Managing Complex Drug Interactions in Underserved Populations <i>Nada Abla Geiser, PharmD, PhD, Director, PBPK Modelling and Clinical Pharmacology, Medicines for Malaria Venture, Switzerland</i>
11:30 – 11:40 a.m.	Discussion
11:40 – 12:00 a.m.	Panel Discussion
12:00 p.m.	Networking Over Lunch
Session IV	In Vitro Assays for Non-CYP Induction? <i>Chair: Ping Zhao</i>
01:30 – 01:55 p.m.	How to study UGT Induction In Vitro and Apply This as an Input for Potential Extrapolation via PBPK <i>Diane Ramsden, Senior Director DMPK, Korro Bio, Inc., Cambridge, United States of America</i>
01:55 – 02:05 p.m.	Discussion
02:05 – 02:30 p.m.	Assessing CYP3A/UGT Co-Induction and its Application for DDI Prediction <i>Xinning Yang, PhD, Clinical Pharmacologist, Ellicott City, Maryland, United States of America</i>
02:30 – 02:40 p.m.	Discussion
02:40 – 03:05 p.m.	Scientific Aspects of PBPK Extrapolation for UGT DDIs: Are We There Yet? <i>Mattia Berton, PhD, PharmD, F. Hoffmann-La Roche Ltd, Switzerland</i>
03:05 – 03:15 p.m.	Discussion
03:15 – 03:30 p.m.	Networking Over Coffee Break & Visiting Posters
Session V	Poster Session <i>Chair: Amin Rostami</i>
03:30 – 04:30 p.m.	Short Presentation & Discussion of Selected Posters
04:30 – 04:45 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 use 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, 31st to June 2nd, 2026	
Venue	Marbach Castle, D-78337 Öhningen +49 (0)7735 – 8130, info@schlossmarbach.de	
Times	May 31st 2026 Afternoon Individual arrival, come together, come together activity, come together dinner, Poster Session, Social Event (Details to be Determined)	
	Scientific Programme June 1 st 2026 Start 09.00 a.m. – Finish 05.00 p.m. June 2 nd 2026 Start 08.30 a.m. – Finish 04.45 p.m.	
Registration & Coffee	May 31 st 2026	03.00 p.m.
	June 1 st 2026	08.00 a.m.

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

Registration

Despite the benefits of personal meeting and networking, we acknowledge that travel restrictions and other limitations may prohibit attendance for some interested colleagues. Therefore, we continue to provide the option for a “hybrid” meeting. Also for the 2026 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

Registration for a web-based virtual conference attendance on June 1st and June 2nd, is possible for the Workshop 2026. 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 Office by:

✉ E-Mail: office@ddi-workshop-marbach.org

or by using the registration form below.

Registration Form

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

3-Day Participation from May 31 st to June 2 nd , 2026	2.250,00 €	<input type="checkbox"/>
3-Day Participation from May 31 st to June 2 nd , 2026, (for members of ACCP or DMDG)	2.150,00 €	<input type="checkbox"/>
2-Day Participation on June 1 st and June 2 nd , 2026 only	2.150,00 €	<input type="checkbox"/>
2-Day Participation on June 1 st and June 2 nd , 2026 only, (in combination with discounted rate for members of ACCP or DMDG)	2.050,00 €	<input type="checkbox"/>
2-Day Participation Virtual Conference on June 1 st and June 2 nd , 2026	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 (245,00 € per night)	<input type="checkbox"/>	<input type="checkbox"/>
double room (325,00 € per night)	<input type="checkbox"/>	<input type="checkbox"/>
Category B: single room (155,00 € per night)	<input type="checkbox"/>	<input type="checkbox"/>
double room (235,00 € per night)	<input type="checkbox"/>	<input type="checkbox"/>
No hotel accommodation required:		<input type="checkbox"/>

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

You may register by

Internet

www.ddi-workshop-marbach.org

E-mail

office@ddi-workshop-marbach.org

Payment

is preferred via bank transfer, but can also be made by credit card, PayPal etc. Upon registration, you will receive an invoice with all payment details.

For further information please contact Dr. Wafaâ Jabrane.

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

Phone: +49(0)176 61 808539

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.

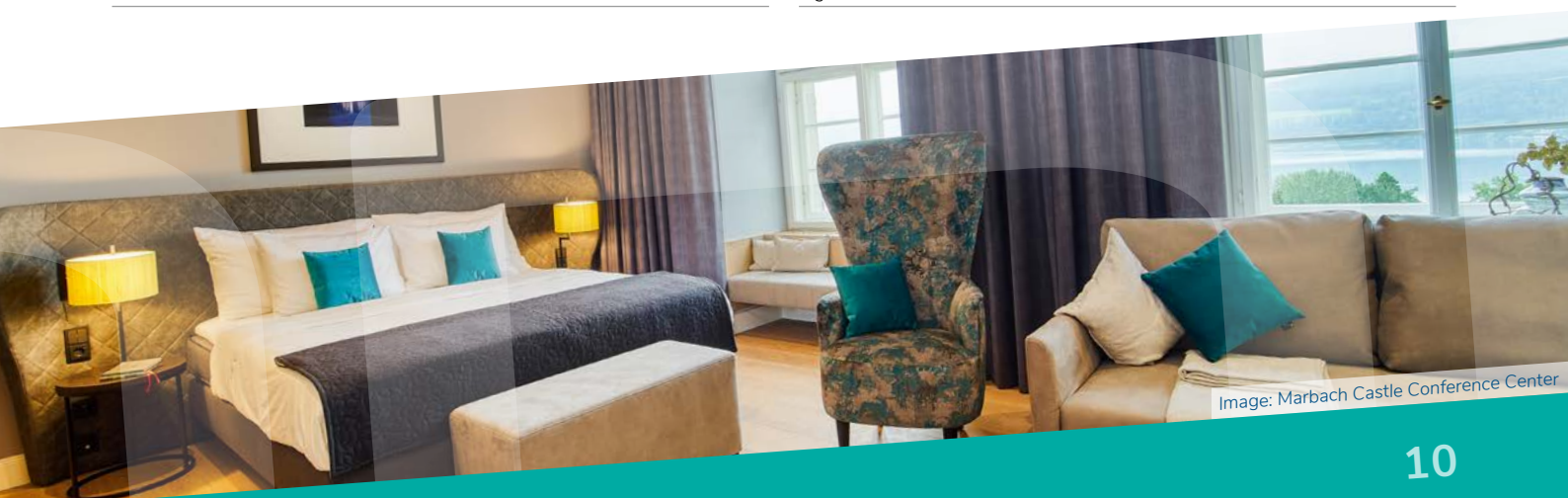


Image: Marbach Castle Conference Center

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 Office: office@ddi-workshop-marbach.org

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



Marbach Map

