

# 25th DGRA Annual Congress

May 4th and 5th, 2023 in Bonn

in the former Assembly Room of the German Bundestag  
(Plenarsaal).

- Reform of EU  
Pharmaceutical  
Legislation
- ICMRA
- Big Data
- EU-HTA
- MDR
- CTIS
- UNICOM Project

**with**

**Prof. Dr. Karl Broich**

Bundesinstitut für Arzneimittel und  
Medizinprodukte (BfArM), Bonn

**Manuela Buxo**

Sanofi Specialty Care, Amsterdam

**Dr. Thomas Ecker**

Ecker + Ecker GmbH, Hamburg

**Dr. Angela Graf**

Kanzlei Lückner MP-Recht, Essen

**Jesper Kjær**

Danish Medicines Agency (DKMA), Kopenhagen

**Riccardo Luigetti**

European Medicines Agency (EMA), Amsterdam

**Dr. Jan Müller-Berghaus**

Paul-Ehrlich-Institut (PEI), Langen

**Georg Neuwirther**

Austrian Medicines and Medical Devices Agency  
(AGES), Wien

**Florian Schmidt**

European Commission, Brüssel

**Khushboo Sharma**

Accumulus Synergy

**Beata Stepniewska**

Medicines for Europe, Brüssel

**Valentina Strammiello**

European Patients' Forum, Brüssel

**PD Dr. Thomas Sudhop**

Bundesinstitut für Arzneimittel und  
Medizinprodukte (BfArM), Bonn

**Wolfgang Witzel**

LORENZ Archiv-Systeme GmbH, Frankfurt

**Moderation:**

**Prof. Dr. Karl Broich**

## The Program on May 4<sup>th</sup> 2023

- 9.30 a.m.**      **Opening and Introduction to Sessions**  
*Dr. Ulrich Granzer*
- 9.45 a.m.**      **Reform of EU Pharmaceutical Legislation  
Concept from the Perspective of the European  
Commission**  
*Florian Schmidt*
- 10.15 a.m.**     **Impact on the Generic Market in the EU**  
*Beata Stepniewska*
- 10.45 a.m.**     **Coffee Break**
- 11.15 a.m.**     **Impact for Research-Based Pharmaceutical Companies**  
*Manuela Buxo*
- 11.45 a.m.**     **Panel Discussion** (*What's in for patients?*)  
*Valentina Strammiello*
- 12.15 a.m.**     **Lunch**
- 1.15 p.m.**      **International Coalition of Medicines Regulatory  
Authorities (ICMRA)**  
• From Crisis Management to better Regulation  
*Riccardo Luigetti*
- 1.45 p.m.**      **Experiences from the Perspective of a National  
Regulatory Authority**  
*Dr. Jan Müller-Berghaus*
- 2.15 p.m.**      **Working together: Concepts beyond eCTD 4.0**  
**Part 1: Accumulus**  
*Khushboo Sharma*  
**Part 2: Docubridge/Access Consortium**  
*Wolfgang Witzel*
- 2.45 p.m.**      **Panel Discussion**

- 3.15 p.m. Coffee Break**
- 3.45 p.m. Relevance of Big Data for Regulatory Procedures**  
*Jesper Kjær*
- 4.15 p.m. Health Data Lab at BfArM – Concepts for Use and Evaluation / Interaction with European Activities (EHDS)**  
*Prof. Dr. Karl Broich*
- 4.45 p.m. Discussion**
- 5.10 p.m. Break** *(no Catering)*
- 5.15 p.m. DGRA General Membership Meeting**  
*(ends around 5.45 p.m.)*
- 7.00 p.m. Pre-Dinner Speech**  
*Reception (6.30 p.m.) and Buffet*

## The Program on May 5<sup>th</sup> 2023

**9.30 a.m.**      **Award Ceremonies “Walter-Cyran-Medaille” and  
“DGRA-Förderpreis”**

**10.00 a.m.**      **The UNICOM Project**  
*Georg Neuwirther*

**10.30 a.m.**      **Upcoming EU-HTA: How can Pharmaceutical  
Industry prepare? Now!**  
*Dr. Thomas Ecker*

**11.15 a.m.**      **Coffee Break**

**11.45 a.m.**      **Clinical Trial Regulation – an Update**  
*PD Dr. Thomas Sudhop*

**12.15 p.m.**      **Medical Device Regulation**

- Implementation Problems
- Extension of the Transitional Periods

*Dr. Angela Graf*

**1.15 p.m.**      **Final Discussion**

**1.30 p.m.**      **Lunch**

**(There may be changes to the program)**

**Dates:**

May 4th, 2023, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions
Followed by General Membership Meeting	5.15 p.m.	
La Redoute	6.30 p.m.	Reception
	7.00 p.m.	Pre-Dinner Speech
May 5th, 2023, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions

**Venue:**

World Conference Center Bonn	La Redoute
Platz der Vereinten Nationen 2	Kurfürstenallee 1
Plenarsaal	D-53177 Bonn
53113 Bonn	

**Registration fees:**

For DGRA members: € 690  
For non-members: € 870

Student discount: Registered students of MDRA course and delegates of organizations (Behörden) who are members of the DGRA: 390 €.

**Cancellation terms:**

Cancellation will be charged with a processing fee of 50 €.

In case of short-term cancellation (2 weeks before) 50 % of the registration fee will be charged.

One week before the event the full fee has to be paid, unless a substitute participant (DGRA member) is named.

**Conference languages:**

English (Morning of May 4th) and German

**Note:**

Photographers will accompany the congress.

Some photographic material will be published.

Congress documents will include a list of participants.

**Room reservation:**

A limited number of rooms are available for participants at special rates in the hotels listed below. When making reservations please refer to "DGRA"/DGRA Annual congress.

Ameron Königshof  
Bonn-Innenstadt  
reservierung@hotel-koenigshof-bonn.de  
keyword „DGRA“

Boutiquehotel Dreesen GmbH & Co.KG  
Mirbachstrasse 2a  
53173 Bonn  
info@boutiquehoteldreesen.de

**More hotel rooms can be booked directly on the internet:**

<https://www.bonn-region.de/events/dgra-jahreskongress-2023.html>

Each participant booking her/his room via the above link of the Tourismus & Congress GmbH will receive a Congress ticket in PDF format with the booking confirmation.

This entitles the participants to use the bus line SB 60 from Airport Cologne / Bonn to Bonn Hbf, the train line 66 from the ICE station Siegburg - Bad Honnef, and other buses and trains within the city of Bonn on arrival and departure day. In addition, participants can use the local public free of charge with the Congress ticket during the Congress in the area of Bonn, Cologne, St. Augustin, Siegburg and Königswinter (Verkehrsverbund Rhein Sieg Area).

**Registration:**

As a DGRA member please use the form at [www.dgra.de](http://www.dgra.de) or contact us at [info@dgra.de](mailto:info@dgra.de)  
DGRA-Geschäftsstelle, Adenauerallee 15, D-53111 Bonn, Fax: +49 (0) 228/368 26 47

The registration is binding. After receipt of the registration a written confirmation will be sent.