

# 26th DGRA Annual Congress

June 20<sup>th</sup> and 21<sup>st</sup>, 2024 in Bonn

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

- Reform of EU Pharmaceutical Legislation
- Platform Technologies and the Definition of Gene Therapies
- Artificial Intelligence in Drug Discovery
- EU and International Exchange
- ePI
- National Pharmaceutical Strategy and Medizinforschungsgesetz
- Clinical Trials

**with**

**Craig Anderson**  
Pfizer, Toronto

**Dr. Michael Berntgen**  
European Medicines Agency (EMA), Amsterdam

**Prof. Dr. Karl Broich**  
Bundesinstitut für Arzneimittel und  
Medizinprodukte (BfArM), Bonn

**Dr. Sandra Fill**  
QYOBO, Ottobrunn

**Dr. Maren von Fritschen**  
Moderna, Netherlands

**Dr. Ulrich Granzer**  
Granzer Regulatory Consulting & Services  
GmbH, München

**Dr. Kowid Ho**  
F. Hoffmann-La Roche, Basel, Schweiz

**Dr. Michael Horn**  
Bundesinstitut für Arzneimittel und  
Medizinprodukte (BfArM), Bonn

**Martin Krauss**  
FGK Clinical Research GmbH, München

**Dr. Dirk Mentzer**  
Paul-Ehrlich-Institut (PEI), Langen

**Georg Neuwirther**  
Austrian Medicines and Medical Devices Agency  
(AGES), Wien

**MinDirig Dr. Lars Christoph Nickel**  
Bundesministerium für Gesundheit (BMG), Bonn

**Rodrigo Palacios**  
F. Hoffmann-La Roche Ltd., Basel

**Dr. Britta Wagenhuber**  
Sanofi-Aventis Deutschland GmbH

**Moderation:**  
**Prof. Dr. Karl Broich**

## The Program on June 20<sup>th</sup> 2024

- 9.30 a.m.**            **Opening and Introduction to Sessions**  
*Dr. Ulrich Granzner*
- 9.45 a.m.**            **The Revision of European Pharmaceutical Legislation,  
National Pharmaceutical Strategy and  
Medizinforschungsgesetz (MFG)**  
*MinDirig Dr. Lars Christoph Nickel*
- 10.15 a.m.**          **National and EMRN Strategies to Foster Innovation  
and Availability**  
*Prof. Dr. Karl Broich*
- 10.45 a.m.**          **New Regulations on Shortages - the National  
Perspective**  
- Causes in the GKV-System  
- Discount Agreements  
*Dr. Michael Horn*
- 11.15 a.m.**          **Coffee Break**
- 11.45 a.m.**          **New Regulations on the Centralized Procedure: Impact  
on the Approval Process and Interactions with HTA**  
*Dr. Michael Berntgen*
- 12.15 p.m.**          **Antibiotics Voucher, how they could work and what a  
Comparable Incentive System has achieved in the US**  
*Dr. Ulrich Granzner*
- 12.45 p.m.**          **(Panel)Discussion**
- 1.15 p.m.**            **Lunch**
- 2.15 p.m.**            **Innovation via New EU Pharma Legislation? Platform  
Technologies and the Definition of Gene Therapies –  
Pharma Industry View**  
*Dr. Maren von Fritschen*

- 2.45 p.m.**      **Discussion**
- 3.00 p.m.**      **Coffee Break**
- 3.20 p.m.**      **Artificial Intelligence in Drug Discovery**
- **Challenges and Future Role of Artificial Intelligence and Machine Learning in Pharmacovigilance**  
*Dr. Dirk Mentzer*
  - **Navigating Compliance Post-COVID with AI and Big Data**  
*Dr. Sandra Fill*
  - **Applications of Virtual Patients in Pharmaceutical Development**  
*Dr. Britta Wagenhuber*
- 4.40 p.m.**      **Discussion and Break (No Catering)**
- 5.00 p.m.**      **DGRA General Membership Meeting**  
*(ends around 5.30 p.m.)*
- 7.00 p.m.**      **Dinner Speech**  
*Reception (6.30 p.m.) and Buffet*

## The Program on June 21<sup>st</sup> 2024

- 9.30 a.m.**      **Global Harmonisation Activities for ATMP**  
*Dr. Kowid Ho*
- 10.15 a.m.**      **Electronic Product Information**  
*Craig Anderson*
- 10.45 a.m.**      **How does eAF, PMS, ePI, Shortage Monitoring fit together**  
*Georg Neuwirther*
- 11.30 a.m.**      **Coffee Break**
- 11.45 a.m.**      **Pharmaceutical Quality Dokumentation and Life Cyclones Management in a Data Driven World - Implikation of ICH Q12, M4Q(R2), SQPS**  
*Rodrigo Palacios*
- 12.30 p.m.**      **Clinical Trials**  
*Martin Krauss*
- 1.15 p.m.**      **Final Discussion**
- 1.30 p.m.**      **Lunch**

(There may be changes to the program)

**Dates:**

June 20th, 2024, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions
Followed by General Membership Meeting	5.00 p.m.	
La Redoute	6.30 p.m.	Reception
	7.00 p.m.	Pre-Dinner Speech
June 21st, 2024, 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: € 750  
For non-members: € 950

**Student discount: Registered students of MDRA course and delegates of organizations (Behörden) who are members of the DGRA: 500 €.**

**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 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.

Boutiquehotel Dreesen GmbH & Co.KG  
Mirbachstrasse 2a  
53173 Bonn  
[info@boutiquehoteldreesen.de](mailto:info@boutiquehoteldreesen.de)

A limited number of rooms are available for participants at the Motel One Bonn-Beethoven. Rooms can be booked with booking form. The form can be requested via [info@dgra.de](mailto:info@dgra.de).

Motel One Bonn-Beethoven  
Bonn Innenstadt  
Tel.: +49 (228) 97 27 86-0  
Fax: +49 (228) 97 27 86-10  
[bonn-beethoven@motel-one.com](mailto:bonn-beethoven@motel-one.com)

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

<https://www.bonn-region.de/events/dgra2024.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.