

24th DGRA Annual Congress

June 27th and 28th, 2022 in Bonn

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

All speakers will participate on site, audience participation is also possible via Zoom.
Please register accordingly.

with

Emer Cooke

European Medicines Agency (EMA),
Amsterdam

Dr. Christa Wirthumer-Hoche

Head of the Austrian Medicines and
Medical Devices Agency, Wien

Prof. Dr. Karl Broich

Bundesinstitut für Arzneimittel und
Medizinprodukte (BfArM), Bonn

Prof. Dr. Klaus Cichutek

Paul-Ehrlich-Institut (PEI), Langen

Dr. Rainer Edelhäuser

Zentralstelle der Länder für
Gesundheitsschutz bei Arzneimitteln und
Medizinprodukten (ZLG), Bonn

Dr. Daniel Ritter

Gemeinsamer Bundesausschuss (G-BA),
Berlin

PD Dr. Thomas Sudhop

Bundesinstitut für Arzneimittel und
Medizinprodukte (BfArM), Bonn

Dr. Sascha Wettmarshausen

VDGH - Verband der Diagnostica-
Industrie e. V., Berlin

Dr. Constanze Blume

BioNTech SE, Mainz

Peter Hergert

ZEPAI Zentrum für Pandemie-Impfstoffe
und –Therapeutika, Langen

Dr. Ulrich Granzer

Granzer Regulatory Consulting &
Services GmbH, München

Moderation:

Prof. Dr. Karl Broich

The Program on June 27th 2022

- 9.30 a.m.** **Opening and Introduction to Sessions**
Ukraine: Update on Development and Production Topics
Dr. Ulrich Granzer, Granzer Regulatory Consulting & Services
- 9.45 a.m.** **The New Mandate of EMA and it`s Consequences**
Emer Cooke, Executive Director EMA
- 10.30 a.m.** **EU Regulatory Network: Challenges after 2 Years Pandemic Situation**
Dr. Christa Wirthumer-Hoche, Head of the Austrian Medicines and Medical Devices Agency
- 11.00 a.m.** **Coffee Break**
- 11.30 a.m.** **The New Health Ecosystem: Medicinal Products, Devices and Big Data – are Regulators prepared?**
Prof. Dr. Karl Broich, President BfArM, Chairperson HMA
- 12.10 p.m.** **Lessons learned from the Pandemic: Vaccines, neutralising Antibodies, Antigen Tests**
Prof. Dr. Klaus Cichutek, President PEI
- 12.50 p.m.** **Panel Discussion**
- 1.00 p.m.** **Lunch**
- 2.00 p.m.** **mRNA – The Next-Generation Cancer Vaccines**
Dr. Constanze Blume, SVP Global Regulatory Affairs, BioNTech SE
- 2.45 p.m.** **Panel Discussion**
- 3.00 p.m.** **Medical Device Regulation (MDR) – an Update**
Dr. Rainer Edelhäuser, Director ZLG
- 3.30 p.m.** **In-Vitro-Diagnostic Device Regulation (IVDR) – an Update**
Dr. Sascha Wettmarshausen, VDGH

4.00 p.m. **Panel discussion**

4.20 p.m. **Coffee Break**

4.45 p.m. **DGRA General Membership Meeting and Board
Elections**
(ends around 5.30 p.m.)

7.00 p.m. **Pre-Dinner Speech**
Reception (6.30 p.m.) and Buffet

The Program on June 28th 2022

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

10.00 a.m. **Aktuelles zum Europäischen HTA-Verfahren**

Dr. Daniel Ritter, G-BA

10.45 a.m. **Nach der Pandemie ist vor der Pandemie: Maßnahmen zur Pandemiebereitschaft und -vorsorge durch das Zentrum für Pandemie-Impfstoffe und -Therapeutika (ZEPAI)**

Peter Hergert, ZEPAI

11.30 a.m. **Coffee Break**

12.00 p.m. **Clinical Trial Regulation – an Update**

PD Dr. Thomas Sudhop, BfArM

1.00 p.m. **Panel Discussion**

1.30 p.m. **Lunch**

(There may be changes to the program)

Dates:

June 27th, 2022, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions
Followed by General Membership Meeting	4.45 p.m.	
Rheinhotel Dreesen	6.30 p.m.	Reception
	7.00 p.m.	Pre-Dinner Speech
June 28th, 2022, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions

Venue:

World Conference Center Bonn	Rheinhotel Dreesen
Platz der Vereinten Nationen 2	Rheinstrasse 45-49 ·
Plenarsaal	D-53179 Bonn
53113 Bonn	

Registration fees:

Participation in face-to-face event:

For DGRA members: € 680

For non-members: € 850

Student discount: Registered students of MDRA course and delegates of organizations (Behörden) who are members of the DGRA: 380 € (face-to-face event), 300 € (virtual)

Participation virtual via Zoom:

For DGRA members: € 550

For non-members: € 720

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 June 27) and German

Note:

Photographers will accompany the workshop.

Some photographic material will be published.

Workshop documents will include two lists of participants (attending and online 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“

Rheinhotel Dreesen
Bonn-Bad Godesberg
Tel.: +49 (0) 228 / 8202-0
info@rheinhoteldreesen.de
keyword „DGRA“

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

Motel One Bonn-Beethoven
Bonn Innenstadt
Booking form available on request at
info@dgra.de

More hotel rooms can be booked directly on the internet:

<https://www.bonn-region.de/events/dgra2022.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 or contact us at 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.