

22nd DGRA Annual Congress

June 18th and 19th, 2020 in Bonn

In the former Assembly Room of the German Bundestag
(Plenarsaal)

- Brexit, Relocation of EMA
- HTA
- Digitalisation of the Healthcare System

with

Dr. Christa Wirthumer-Hoche
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 (Zusage unter
Vorbehalt)**
Zentralstelle der Länder für Gesundheitsschutz
bei Arzneimitteln und Medizinprodukten (ZLG),
Bonn

Prof. Burkhard Sträter
Kanzlei Sträter Rechtsanwälte, Bonn

Dr. Isabell Stöckert
Bayer AG, Wuppertal

Dr. Ulrich Granzer
Granzer Regulatory Consulting & Services,
München

Thomas Müller
Bundesministerium für Gesundheit (BMG),
Berlin

Dr. Anna Silke Hammerbacher
Daiichi-Sankyo Europe GmbH, München

PD Dr. Thomas Sudhop
Bundesinstitut für Arzneimittel und
Medizinprodukte (BfArM), Bonn

Dr. Andreas Franken
Bundesverband der Arzneimittel-Hersteller e.V.
(BAH), Bonn

Moderation:
Prof. Dr. Karl Broich and
Prof. Burkhard Sträter

The Program on June 18th 2020

- 9.30 a.m. Opening of the Annual Congress and Introduction to Sessions**
Dr. Ulrich Granzer, Granzer Regulatory Consulting & Services
- 9.45 a.m. EMA in Amsterdam - Set for the Future**
N.N.
- 10.30 a.m. Challenges in the EU-Network - Perspectives from Management Board and NCA**
Dr. Christa Wirthumer-Hoche, Chairman of Management Board EMA, Head of the Austrian Medicines and Medical Devices Agency
- 11.00 a.m. Coffee Break**
- 11.30 a.m. BfArM Reloaded - Eingliederung des DIMDI**
Prof. Dr. Karl Broich, President BfArM
- 12.00 p.m. Änderungen bei EMA, DIMDI, BfArM - Industriesicht**
Dr. Isabell Stöckert
- 12.30 p.m. Panel discussion**
- 12.45 p.m. Lunch / Dinner**
- 1.45 p.m. Nutzen-Risiko-Evaluation bei Impfstoffen und biomedizinischen Arzneimitteln**
Prof. Dr. Klaus Cichutek, President PEI
- 2.30 p.m. Medical Device Regulation EU – an Update**
Dr. Rainer Edelhäuser, ZLG
- 3.15 p.m. EU-HTA-Regulation**
 ➤ Status of Procedure – German Positions and Initiatives
Thomas Müller, BMG
- 3.45 p.m. HTA meets Regulatory Affairs**
Dr. Anna Silke Hammerbacher, Daiichi-Sankyo Europe GmbH
- 4.15 p.m. Panel discussion**
- 4.30 p.m. Coffee Break**

4.45 p.m. DGRA General Membership Meeting

(ends around 5.30 p.m.)

7.00 p.m. Pre-Dinner Speech

Reception (6.30 p.m.) and Buffet

The Program on June 19th 2020

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

10.00 a.m. Measures in Germany

- Electronic Patient Record acc. to DVG
- Electronic Recipes acc. to GSAV
- Medical Apps on Prescription acc. to DVG
- Elektronische Arzneimittelinformations-Verordnung (EAMIV)
- Transformation of G-BA Assessment Prescribing Physicians

Prof. Burkhard Sträter, Kanzlei Sträter Rechtsanwälte

10.45 a.m. Digitalisation of the Healthcare System

Electronic Product Information (e-PI)

- Common Project: EU-Commission / HMA / EMA
- Development of Draft Key Principles
- Comments from Industry

Dr. Andreas Franken, BAH

11.30 a.m. Coffee Break

12.00 p.m. Clinical Trial Regulation – an Update

- Outcomes of Pilot Procedures in BfArM

PD Dr. Thomas Sudhop, BfArM

1.00 p.m. Panel discussion

1.30 p.m. Lunch / Dinner

(There may be changes to the program)

Dates:

June 18, 2020, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions
Followed by General Membership Meeting	4.45 p.m.	
Hotel Königshof	6.30 p.m.	Reception
	7.00 p.m.	Pre-Dinner Speech
June 19, 2020, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions

Venue:

World Conference Center Bonn Platz der Vereinten Nationen 2 Plenarsaal 53113 Bonn	Hotel Königshof Adenauerallee 15 D-53111 Bonn
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Registration fees:

For DGRA members: € 680
For non-members: € 830

Student discount: Registered students of MDRA course and delegates of organizations (Behörden) who are members of the DGRA: € 360

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 18) and German

Note:

Photographers will accompany the workshop.
Some photographic material will be published.

Workshop 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.

Rheinhotel Dreesen
Bonn-Bad Godesberg
Tel.: +49 (0) 228 / 820 20

Ameron Königshof
Bonn-Innenstadt
Tel.: +49 (0) 228 / 260 10

Boutiquehotel Dreesen GmbH & Co. KG
Villa Godesberg
Bonn-Bad Godesberg
Tel.: +49 (0) 228 / 830 060
info@boutiquehoteldreesen.de

Intercity Hotel
Bonn-Innenstadt
+49 228 / 926 18 10

More hotel rooms can be booked directly on the internet:

<https://www.bonn-region.de/dgra-jahreskongress-2020.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.