

# 21st DGRA Annual Congress

**May 23th and 24th, 2019 in Bonn**

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

- Brexit, Relocation of EMA
- Big Data
- Clinical Trials
- Neue Gesetzgebungsverfahren
- Medizinprodukte-Verordnung – aktueller Sachstand

with

**Prof. Dr. Guido Rasi**

European Medicine Agency (EMA), London /  
Amsterdam

**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

**Nikolai C. Brun**

Danish Medicines Agency (DKMA), Copenhagen

**Thomas Müller**

Bundesministerium für Gesundheit (BMG),  
Berlin

**Dr. Mark Goldammer**

Paul-Ehrlich-Institut (PEI), Langen

**Dr. Ulrich Granzer**

Granzer Regulatory Consulting & Services,  
München

**Prof. Burkhard Sträter**

Kanzlei Sträter Rechtsanwälte, Bonn

**Dr. Isabelle Stöckert**

Bayer AG, Wuppertal

**Dr. Heike Wollersen**

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

**Moderation: Prof. Burkhard Sträter**

Kanzlei Sträter Rechtsanwälte, Bonn

## The Program on May 23th 2019

- 9.30 a.m.**            **Opening of the Annual Congress and introduction to Sessions**  
*Dr. Ulrich Granzer, Granzer Regulatory Consulting & Services*
- 9.45 a.m.**            **Relocation of EMA, Challenges and Consequences**  
*Prof. Guido Rasi - Executive Director EMA*
- 10.30 a.m.**          **Realignment of the EU-network: Perspectives from the 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.**          **Impact of the Brexit from an Industrial Perspective**  
*Dr. Isabelle Stöckert, Bayer AG*
- 12.00 p.m.**          **HMA / EMA Joint Big Data Task force initiative  
Presentation of the Report and next steps**  
*Nikolai C. Brun, Chair of joint HMA/EMA Task Force on Big Data; DKMA*
- 12.45 p.m.**          **Lunch**
- 1.45 p.m.**            **From Big Data to Real World Data: hype or meaningful for regulators?**  
*Prof. Dr. Karl Broich, President BfArM*
- 2.30 p.m.**            **Application of Big Data strategies and technologies in proteomics and individualised therapeutic vaccines**  
*Dr. Mark Goldammer, Member of joint HMA/EMA Task Force on Big Data; PEI*
- 3.00 p.m.**            **Clinical Trials: First in men and complex study designs**  
*Prof. Dr. Klaus Cichutek, President PEI*

- 3.45 p.m. Panel discussion**
- 4.15 p.m. Coffee Break**
- 4.30 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 May 24th 2019**

- 9.30 a.m. Award Ceremonies “Walter-Cyran-Medaille”  
and “DGRA-Förderpreis“**
- 10.00 a.m. Einleitung zu neuen Gesetzgebungsverfahren**  
*Prof. Burkhard Sträter, Kanzlei Sträter Rechtsanwälte*
- 10.30 a.m. Die neue Medizinprodukte-Verordnung –  
aktueller Sachstand**  
*Dr. Heike Wollersen, BAH*
- 11.15 a.m. Panel discussion**
- 11.30 a.m. Coffee Break**
- 12.00 p.m. Arzneimittelüberwachung, ATMPs und Post-  
Marketing-Daten: Aktuelle Gesetzesvorhaben**  
*Thomas Müller, BMG*
- 1.00 p.m. Panel discussion**
- 1.30 p.m. Lunch / Dinner**

**(There maybe changes to the program)**

**Dates:**

May 23, 2019, Plenarsaal, Bonn	9.30 a.m.	Presentations and discussions
Followed by General Membership Meeting	4.30 p.m.	
Rheinhotel Dreesen	6.30 p.m.	Reception
	7.00 p.m.	Pre-Dinner Speech
May 24, 2019, 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:**

For DGRA members: € 680	Student discount: Registered students of MDRA course and delegates of organizations (Behörden) who are members of the DGRA: € 360
For non-members: € 830	

**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 23) 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 / 8202-0

**HOTEL MYPOPPELSDORF**  
Bonn-Innenstadt  
Tel.: +49 (0) 228 26 910

Hotel Rheinland Bad Godesberg  
Bonn-Bad Godesberg  
Tel.: +49 (0) 228 / 82 00 0-0

**Intercity Hotel**  
Bonn-Innenstadt  
+49 228 926181-0

**Bonn Marriott Hotel**

Direkt am Veranstaltungsort

Buchung nur über folgenden Link:

<https://www.marriott.com/events/start.mi?id=1551945424992&key=GRP>

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

<http://www.bonn-region.de/events/dgra-2019.html>

Each participant booking 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.