

17th DGRA Annual Congress

7 and 8 May, 2015 in Bonn

Clinical Trial Regulation, Pharmacovigilance

- Clinical Trial Regulation
- Transparency
- Pharmacovigilance

with

Dr. Dagmar Chase

BVMA e.V. - Federal Association of
Contract Research Organisations, Munich

Dr. Dagmar Dörmann

Federal Ministry of Health (BMG), Bonn

Dr. Ulrich Granzer

Granzer Regulatory Consulting & Services,
Munich

Dr. Petra Kammann

Boehringer Ingelheim Pharma GmbH & Co
KG, Ingelheim

Dr. Hartmut Krafft

Paul-Ehrlich Institute (PEI), Langen

Min Rat Dr. Lars-Christoph Nickel

Federal Ministry of Health (BMG), Bonn

Dr. Norbert Paeschke

Federal Institute for Drugs and Medical
Devices (BfArM), Bonn

Dr. June Munro Raine

Medicines and Healthcare Products
Regulatory Agency (MHRA), PRAC Chair
EMA, London

Prof. Dr. Barbara Sickmüller

DGRA e.V., Bonn

PD Dr. Thomas Sudhop

Federal Institute for Drugs and Medical
Devices (BfArM), Bonn

Moderation: Prof. Burkhard Sträter

Kanzlei Sträter Rechtsanwälte, Bonn

The Program on May 7, 2015

Moderator: Prof. Burkhard Sträter, Attorney

9.30 am Opening of the Annual Congress and introduction to sessions, Dr. Ulrich Granzer

**09.45 am I. Clinical Trial Regulation –
accompanying national rules**
Min Rat Dr. Lars-Christoph Nickel, BMG

**II. Clinical Trial Regulation – challenges for
National Competent Authorities**

a) Perspective of PEI
Dr. Hartmut Krafft, PEI

II. b) Perspective of BfArM
PD Dr. Thomas Sudhop, BfArM

11.00 am Coffee break

**11.30 am III. Clinical Trial Regulation -
a) Perspective of the Pharmaceutical Industry**
Prof. Dr. Barbara Sickmüller, DGRA

b) Perspective of the CROs
Dr. Dagmar Chase, BVMA Chair

12.15 pm Panel Diskussion

12.45 pm Lunch break

**2.15 pm IV. EU-Portal for CTAs and
EUDRA CT Database Update**
Dr. Dagmar Dörmann, BMG

3.00 pm V. EMA Transparency policy §42b

- Freedom of information act
- Legal assessment
- Clinical trials data

Prof. Burkhard Sträter, Kanzlei Sträter Rechtsanwälte

3.30 pm Panel Discussion with all Speakers

3.45 am Coffee break

4.15 pm DGRA Members' Meeting
(ends at around 6.00 pm)

7.00 pm Pre-dinner Speech

Reception and buffet

The Program on May 8, 2015

9.30 am “Walter-Cyran-Medaille” award

10.00 am VI. Pharmacovigilance Referral

*Dr. June Munro Raine,
MHRA, PRAC Chair EMA*

11.00 am Coffee break

11.30 am VII. National Pharmacovigilance Update

- Educational material
- DHPC
- Anwendungsbeobachtungen
- Impact of selected new EU-Guidance documents

*Dr. Norbert Paeschke,
Head of Pharmacovigilance BfArM*

**12.15 pm VIII. Experiences with a referral procedure Art 31
on an OTC-product: A company perspective**

- What was the trigger?
- Thoughts around a Response-Strategy
- Special challenges for an OTC-product
- Response and List of outstanding issues
- Oral explanation meeting
- Lessons learned

*Dr. Petra Kammann,
Boehringer Ingelheim Pharma GmbH & Co KG*

1.00 pm Panel Discussion with all speakers

1.15 pm Lunch / Snack

(Program subject to change without prior notice)

Dates:

May 7, 2015 Wasserwerk 9.30 am
Followed by 4.00 pm
Hotel Königshof 7.00 pm

Presentations and Discussions
DGRA Members' Meeting
Pre-Dinner Speech, Reception

May 8, 2015 Wasserwerk 9.30 am

Presentations and Discussions

Presentations and discussions

Venue:

Wasserwerk Bonn
Charles-de-Gaulles-Str/
Hermann-Ehlers-Straße
Entrance V
D-53113 Bonn

Hotel Königshof
Adenauerallee 15
D-53111 Bonn

Cost contribution:

For DGRA members: € 460

For non-members: € 590

Student price: Students of MDRA course (MDRA XIV and XV) and delegates of bodies (Behörden) who are members of the DGRA: € 260

Cancellation terms:

Up to two weeks before the first day of the conference (23-April-2015): € 50; up to one week before the first day of the conference (30-April-2015): 50% of fee; late cancellations: full conference fee if a substitute participant (DGRA member) cannot be put forward. In the event of cancellation by the organizer, any fees already paid will be fully reimbursed.

Conference languages:

English and German

Some photographic material will be published.

Note:

Photographers will accompany the workshop.

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"/this event.

Hotel Königshof
Bonn-Innenstadt
Tel.: + 49 (0) 228-26010

Hotel Hilton
Bonn-Innenstadt
Tel: +49 (0) 228 / 72 69-0

Galerie Design Hotel Bonn
Bonn-Nordstadt
Telefon: +49 (0) 228 1848-0

Kameha Grand Bonn
Bonn-Oberkassel
Tel: +49 (228) 43 34 50 00

Hotel (Günnewig) Residence
Bonn-Innenstadt (Bhf)
Tel: +49 (0) 228 / 26 97-0

Villa Godesberg
Bonn-Bad Godesberg
Tel.: +49 (0) 228 / 83 006-0

More hotel rooms can be booked directly on the internet:

<http://www.bonn-region.de/events/17-jahreskongress.html>

Each participant booking his room via the above link of the Tourismus & Congress GmbH, receives with the booking confirmation a Congress ticket in PDF format.

It entitles the participants to use the bus line SB 60 from Airport Cologne / Bonn to Bonn Hbf ; 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 transport with the Congress ticket during the Congress for free in the area of Bonn, Köln, 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