

27th DGRA Annual Congress

May 8th and 9th, 2025 in Bonn

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

- > HTA
- > DIGA
- ➤ Medicines Research Act
- > Trends in Animal Health

- ➤ AI in Drug Development and Medical Devices
- ➤ MDR and IVDR
- Successful Spin-Off

with

Dr. Peter Arlett

European Medicines Agency (EMA), Amsterdam

Dr. Andreas Bonertz

Paul-Ehrlich-Institut (PEI), Langen

Prof. Dr. Karl Broich

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Bonn

Dr. Rainer Edelhäuser

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

Prof. Dr. Stefan Engelhardt

rnatics GmbH, Martinsried

Yves Jacob

Sanofi

Dr. Heather Johnson

Granzer Regulatory Consulting & Services GmbH, München

Dr. Niels Krebsfänger

Elanco Animal Health GmbH, Monheim am Rhein

Dr. Niklas Rach

Tensor AI Solutions GmbH, Ulm

Prof. Dr. Folker Spitzenberger

Technische Hochschule Lübeck

Dr. Isabelle Stöckert

Köln

Dr. Beate Wieseler

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), Köln

Moderation:

Prof. Dr. Karl Broich

The Program	on May	8 th 2025
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2.45 p.m.

Health

Dr. Peter Arlett

Opening and Introduction to Sessions 9.30 a.m. Dr. Ulrich Granzer 9.45 a.m. **Joint Health Technology Assessment across Europe:** The EU HTA Regulation Coming into Effect Dr. Beate Wieseler 10.15 a.m. The New Parallel Regulatory and HTA Processes in the **EU - Opportunities and Challenges** Dr. Isabelle Stöckert 10.45 p.m. Discussion Coffee Break 11.00 a.m. From Idea to a Clinical-Stage Company. 11.30 a.m. Macrophage-Targeted RNA Therapeutics Prof. Dr. Stefan Engelhardt 12.00 a.m. **Artificial Intelligence – How will AI/ML Tools** transform Regulatory Practice? Yves Jacob 12.30 p.m. Discussion 12.45 p.m. Lunch AI and Medical Devices: Challenges and Opportunities 1.45 p.m. Prof. Dr. Folker Spitzenberger 2.15 p.m. **Future Research Pharma** Practical Insights into the Use of AI in Companies Dr. Niklas Rach

Leveraging the Power of Data for Public and Animal

3.15 p.m. **Discussion Coffee Break** 3.30 p.m. 3.45 p.m. **Quo vadis MDR?** Dr. Rainer Edelhäuser 4.15 p.m. **Issues Arising from the Implementation of the IVDR** for Industry Dr. Heather Johnson 4.45 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 May 9th 2025

9.30 a.m. Award Ceremonies "Walter-Cyran-Medaille" and "DGRA-Förderpreis"

10.00 a.m. Lecture of the Winner "DGRA-Förderpreis"

10.30 a.m. Trends in Animal Health: VMPs as Crucial Part of the One Health Concept

Dr. Niels Krebsfänger

11.00 am Coffee Break

11.30 a.m. Medicines Research Act - New Opportunities for Germany

Dr. Andreas Bonertz

12.00 p.m. Digital Health Applications-Current Status and

Challenges

Prof. Dr. Karl Broich

12.45 p.m. Final Discussion

1.15 p.m. Lunch

(There may be changes to the program)

Dates:

May 8th, 2025, Plenarsaal, Bonn 9.30 a.m. Presentations and discussions

Followed by General Membership Meeting 5.00 p.m.

Hotel Königshof 6.30 p.m Reception

Pre-Dinner Speech 7.00 p.m.

9.30 a.m. May 9th, 2025, Plenarsaal, Bonn Presentations and discussions

Venue:

World Conference Center Bonn Hotel Königshof Platz der Vereinten Nationen 2 Adenauerallee 9 Plenarsaal D-53111 Bonn 53113 Bonn

Registration fees:

Student discount: Registered students of For DGRA members: € 780 MDRA course and delegates of organizations For non-members: (Behörden) who are members of the DGRA:

520 €.

Cancellation terms:

Cancellation will be charged with a processing fee of 50 ϵ .

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

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.

Ameron Bonn Hotel Königshof

Bonn Innenstadt

reservierung@hotel-koenigshof-bonn.de

Abrufkontingent vom 07.05.2025-09.05.2025, Stichwort: "DGRA2025"

Abrufende: 26.03.2025, danach nach Verfügbarkeit.

Boutiquehotel Dreesen GmbH & Co.KG

Bonn-Bad Godesberg Tel.: +49 (0) 228 8300-60 info@boutiquehoteldreesen.de

More hotel rooms can be booked directly on the internet:

https://www.bonn-region.de/events/dgra-jahreskongress2025.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.