

28th DGRA Annual Congress

June 18th and 19th, 2026 in Frankfurt Gravenbruch

Hotel Hilton

- EU Pharma Package & regulatory reforms
- Medical Research Act & Pharma Dialogue
- ATMPs & Biologics: Clinical research
- EU HTA & EMA collaboration
- Competitiveness, sustainability & ESG
- AI, real-world evidence & health data ecosystems
- Startups & Innovation in Pharma

with

Dr. Michael Berntgen

European Medicines Agency (EMA), Amsterdam

N.N. (angefragt)

Granzer Regulatory Consulting & Services GmbH, München

Prof. Dr. Karl Broich

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Bonn

Dr. Ulrich Granzer

Granzer Regulatory Consulting & Services GmbH, München

Dr. Steffen Heß

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Bonn

N.N. (angefragt)

Roche Group

N.N. (angefragt)

Bundesministerium für Gesundheit (BMG), Bonn

Luis Pinheiro

European Medicines Agency (EMA), Amsterdam

Dr. Grzegorz Popowicz

Institut für Strukturbioogie, Helmholtz Zentrum München

Dr. Florian Schmidt

European Commission, Brussel

PD Dr. Thomas Sudhop

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Bonn

Prof. Dr. Stefan Vieths

Paul-Ehrlich-Institut (PEI), Langen

Dr. Beate Wieseler

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

N.N. (angefragt)

Sanofi

Moderation:

**Prof. Dr. Karl Broich and
Dr. Ulrich Granzer**

The Program on June 18th 2026

- 9.30 a.m. Opening and Introduction to Sessions**
Dr. Ulrich Granzer (CEO Granzer Regulatory Consulting & Services)
- 9.45 a.m. The EU Pharma Package - Setting the Course for Research and innovation and an attractive regulatory system**
Dr. Florian Schmidt (Deputy Head of Unit, DG SANTE, European Commission)
- 10.15 a.m. Updates on the Medical Research Act and Pharma Dialogue**
Prof. Dr. Karl Broich (President Federal Institute for Drugs and Medical Devices (BfArM))
- 10.45 p.m. The Paul-Ehrlich-Institute: Role in ATMPs and Biologics Regulation**
Prof. Dr. Stefan Vieths (President Paul-Ehrlich-Institute (PEI))
- 11.15 a.m. Discussion**
- 11.30 a.m. Coffee Break**
- 12.00 a.m. EU HTA in Practice: First Experiences from Oncology and ATMPs**
Dr. Beate Wieseler (Head of Drug/Medicines Evaluation, Institute for Quality and Efficiency in Health Care (IQWiG))
- 12.30 p.m. From Approval to Access: Evolving Collaboration between EMA and HTA at the Interface**
Dr. Michael Berntgen (Head of Scientific Evidence Generation Department, European Medicines Agency (EMA))
- 1.00 p.m. Discussion**
- 1.15 p.m. Lunch**

- 2.15 p.m.** **Current Developments in the Pharma Dialogue: The 5% Rule as a Competitive Advantage?**
N.N. (BMG)
- 2.45 p.m.** **Environmental and Sustainability Requirements in the New EU Pharmaceutical Legislation**
N.N. (Sanofi)
- 3.15 p.m.** **Discussion**
- 3.30 p.m.** **Coffee Break**
- 3.45 p.m.** **Clinical Research in Germany: Opportunities Arising from New Legal Frameworks**
PD Dr. Thomas Sudhop (Senior Expert for Clinical Trials, BfArM)
- 4.15 p.m.** **Thoughts/Expectations from Big Pharma for the Work with Biotech Startups**
N.N. (Roche Group)
- 4.45 p.m.** **Discussion and Break (No Catering)**
- 5.00 p.m.** **DGRA General Membership Meeting and Board Elections**
(ends around 5.45 p.m.)
- 7.00 p.m.** **Dinner Speech**
Reception (6.30 p.m.) and Buffet

The Program on June 19th 2026

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

10.00 a.m. AI in Drug Development

Dr. Grzegorz Popowicz (Research Group Leader, Institute of Structural Biology, Helmholtz Center Munich)

**10.30 a.m. Research Data Centers
(Forschungsdatenzentrum(FDZ)) and the European
Health Data Space**

Dr. Steffen Heß (Head of Health Data Lab, BfArM)

11.00 am Coffee Break

11.30 a.m. AI & Real-World Evidence

Luis Pinheiro (Senior Epidemiology Expert, RWE, Data Analytics and Methods Taskforce, EMA)

**12.00 p.m. Startups Between Innovation and Regulation –
Collaboration with Authorities**

N.N.

12.45 p.m. Panel Discussion

1.30 p.m. Lunch

(There may be changes to the program)

Dates:

June 18th, 2026, Hotel Hilton Gravenbruch	9.30 a.m.	Presentations and discussions
Followed by General Membership Meeting	5.00 p.m.	
Hotel Hilton Gravenbruch	6.30 p.m.	Reception
	7.00 p.m.	Pre-Dinner Speech
June 19th, 2026, Hotel Hilton Gravenbruch	9.30 a.m.	Presentations and discussions

Venue:

Hilton Frankfurt Gravenbruch
Graf-zu-Ysenburg-und-Büdingen-Platz 1
63263 Neu-Isenburg

Registration fees:

Congress only (without accommodation): €560
Early Bird*: €495

Congress + 1 night accommodation: €755
Early Bird*: €690

Congress + 2 nights accommodation: €950
Early Bird*: €885

Accommodation includes: breakfast, Wi-Fi, and access to spa & fitness area.

Note: Rooms are limited and assigned on a first-come, first-served basis.

Payment & Confirmation: After registration, you will receive confirmation and payment details. Hotel bookings are handled by the congress office - no separate booking required.

VAT Information: As a non-profit association, fees are VAT exempt.

Student discount:

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

Congress only (without accommodation): €360
Early Bird*: €320

Congress + 1 night accommodation: €555
Early Bird*: €515

Congress + 2 nights accommodation: €750
Early Bird*: €710

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* Book now and save! Early bird tickets are available at reduced rates. Offer valid until 20 March 2026

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.

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

The registration is binding. After receipt of the registration a written confirmation will be sent.

Conference languages:

English and German

Note:

Photographers will accompany the congress.

Some photographic material will be published.

Congress documents will include a list of participants.