

# 18. DGRA Jahreskongress

15. und 16. Juni 2016 in Bonn

## Adaptive Pathways, Clinical Trial Regulation, Identification of Medicinal Products

- Adaptive Pathways
- Priority medicines (PRIME) scheme
- HTA, Intellectual Property
- Clinical Trial Regulation - 4. Änderungsgesetz Implementierung ins AMG

mit

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**Min Rat Dr. Lars-Christoph Nickel**  
Federal Ministry of Health (BMG), Bonn

**Dr. Aylin Mende**  
Federal Institute for Drugs and Medical  
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**Thomas Müller**  
Federal Joint Committee (G-BA), Berlin

**Dr. Harald Tietz**  
Lilly Deutschland GmbH, Bad Homburg

**Moderation: Prof. Burkhard Sträter**  
Kanzlei Sträter Rechtsanwälte, Bonn

# Das Programm am 15. Juni 2016

**Moderation: Prof. Burkhard Sträter**

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

**09.45 Uhr**    **I. Adaptive Pathways**  
**Goals of EMA and National Competent Authorities**  
*PD Dr. Harald Enzmann, BfArM*

**II. Adaptive Pathways**  
**Experiences and Perspective**  
**of the Pharmaceutical Industry**  
*Dr. Ulrich Granzer, Granzer Consulting*

**11.00 Uhr**      **Kaffeepause**

**11.30 Uhr**    **III. Priority medicines (PRIME) scheme**  
*Christelle Bouygues, EMA*

**12.15 Uhr**    **Panel Discussion**

**12.45 Uhr**      **Mittagessen**

**14.15 Uhr**    **IV. Adaptive Pathways - Einfluss auf**  
▪ den Unterlagenschutz  
▪ die ergänzenden Schutzzertifikate  
*Prof. Burkhard Sträter, Kanzlei Sträter Rechtsanwälte*

**15.00 Uhr**    **V. Konsequenzen für die frühe Nutzenbewertung**  
▪ Adaptive Pathways: Experiences in Germany and challenges for national HTA  
▪ Post-Marketing-Evidence  
▪ European Early Dialogue: Recent developments, GBA position  
*Thomas Müller, G-BA*

**15.30 Uhr**    **Panel Diskussion mit allen Referenten**

**15.45 Uhr**      **Kaffeepause**

**16.15 Uhr**    **DGRA Mitgliederversammlung**  
(endet gegen 17.30 Uhr)

**19.00 Uhr**    **Pre-dinner Speech**  
*Reception and buffet*

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## Das Programm am 16. Juni 2016

**9.30 Uhr**    **“Walter-Cyran-Medaille” Preisverleihung**

**10.00 Uhr**    **VI. Clinical Trial Regulation –**  
**4. Änderungsgesetz Implementierung ins AMG**  
*Min Rat Dr. Lars-Christoph Nickel, BMG*

**10.30 Uhr**    **VII. Clinical Trial Regulation –**  
**Herausforderung für die nationalen Behörden**  
*Dr. Aylin Mende, BfArM*

**11.15 Uhr**    **Kaffeepause**

**11:45 Uhr**    **VIII. Clinical Trial Regulation –**  
**Sicht der Pharmazeutischen Industrie**  
*Dr. Harald Tietz, Lilly Deutschland GmbH*

**12.15 Uhr**    **IX. IDMP (Identification of Medicinal Products)**  
**Sachstand der IDMP Entwicklung bei ICH und ISO**  
**aus Sicht der Industrie und der Verbände**

- Inhalte der einzelnen IDMP Standards
- ISO Implementation Paper 1872 Core Principles  
for Maintenance of Identifiers and Terms
- GInAS - Global Ingredient Archival System
- EDQM Datenbank zu Standard Terms

*Dr. Andreas Franken, BAH*

**13.30 Uhr**    **Panel Diskussion mit allen Referenten**

**14.00 Uhr**    **Mittagessen / Imbiss**

**(Programmänderungen sind möglich)**

**Dates:**

**June 15, 2016 WCC, Bonn 9.30 am**  
**Followed by 4.00 pm**  
**Hotel Königshof 7.00 pm**

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

**June 16, 2016 WCC, Bonn 9.30 am**

**Presentations and Discussions**

**Presentations and discussions**

**Venue:**

**World Conference Center (WCC) Bonn**  
**Platz der Vereinten Nationen 2**  
**Charles-de-Gaulles-Str/**  
**D-53113 Bonn**

**Hotel Königshof**  
**Adenauerallee 15**  
**D-53111 Bonn**

**Cost contribution:**

**For DGRA members: € 560**  
**For non-members: € 700**

**Student price: Students of MDRA course (MDRA XVI and XVII) and delegates of bodies (Behörden) who are members of the DGRA: € 300**

**Cancellation terms:**

**Up to two weeks before the first day of the conference (1-June-2016): € 50; up to one week before the first day of the conference (8-June-2016): 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 (Morning of June 15) 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**

**Marriott Hotel Bonn**  
**Bonn-Gronau (neben dem World**  
**Conference Center)**  
**Tel.: +49 (0) 228 280 500**

**Maritim Hotel Bonn**  
**Bonn-Hochkreuz**  
**Telefon: +49 (0) 228 81080**

**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/dgra-2016.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](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****