

AEREON CONSULTING & PHARMA SERVICES ANNOUNCES THE

# 3<sup>RD</sup> MASTERCLASS RESPIRATORY TRIALS 2017

SUPPORTED BY INSAF RESPIRATORY RESEARCH INSTITUTE

Includes  
New FDA 2016  
COPD guidance  
and AMNOG  
amendments!

**AEREON**  
CONSULTING & PHARMA SERVICES



**insaf**  
Respiratory Research Institute



## BACKGROUNDER:

Asthma and COPD are common chronic disorders with high global burden of morbidity and mortality. The respiratory market for pharmaceuticals is expected to grow substantially in the upcoming years, making the area an attractive field for therapeutic developments. The design of clinical trials is pivotal for the development of any new drug, including the appropriate choice of patient populations, endpoints, methodology, and comparator treatments. With the landscape becoming more competitive and in light of increasing demands from health technology bodies, the challenge of successful market access for new therapeutics from molecule to practical application is ever growing.

## TOPICS:

Learn the fundamentals of clinical trial design in asthma and COPD. Understand basic lung anatomy and respiratory physiology, as well as key methods to evaluate outcomes in trials including objective assessments and PROs. Get familiar with current treatment strategies and unmet clinical needs. Identify challenges in choices of study populations, trial design and outcomes. Learn of regulatory requirements for drug approval and the growing impact of HTA processes on drug reimbursement. Understand the environment of HTA in Europe and get familiar with the most recent experience with the national German process of early post-marketing value assessment (AMNOG). Enjoy a hands-on practical session for relevant respiratory outcome measures including spirometry, plethysmography, and exercise testing.


## WHO SHOULD ATTEND?

Industry Executives, Officers, Scientist, Project Leaders, etc. involved in Respiratory Medicine or Pharmacology, Therapeutic Development, Medical Sciences, R&D, Market Access etc.

## YOUR SPEAKERS:

The involved speakers sum up experience of over 15 years in respiratory clinical research, with more than 100 trials planned, designed and conducted. External speaker(s) are renowned international experts in the field of asthma and COPD.

# AGENDA 3<sup>RD</sup> MASTERCLASS RESPIRATORY

 DAY 1	10 <sup>TH</sup> MARCH 2017	
10.30 – 10.45	Welcome and Introduction	(All)
10.45 – 11.30	Respiratory Anatomy and Airway Pathology	(Beier)
11.30 – 13.00	Clinical Methodology in Respiratory Medicine <i>Pulmonary Function Testing, Challenge Models, Airway Monitoring etc.</i>	(Beeh)
13.00 – 14.00	Lunch	
14.00 – 14.45	Asthma Clinical Background <i>Epidemiology, Treatment Strategies (GINA), Unmet Needs</i>	(N.N.)
14.45 – 15.30	COPD Clinical Background <i>Epidemiology, Treatment Strategies (GOLD), Unmet Needs</i>	(N.N.)
15.30 – 16.15	PROs in Asthma and COPD Trials, Part 1: <i>Regulations, Applications, Limitations – Examples</i>	(Beier)
16.15 – 16.30	Afternoon Coffee Break	
16.45 – 17.15	PROs; Part 2: <i>What is “meaningful?” Issues around MCIDs</i>	(Beeh)
17.15-17.30	Q/A, Discussion	(All)
17.30	End of Day 1	
19.00	Meeting for Dinner at “Käfer’s Bistro”, Wiesbaden	(All)

## Venue:

Dorint Hotel Wiesbaden /  
insaf Respiratory Research Institute,  
Biebricher Allee 34,  
D-65187 Wiesbaden, Germany



## Time:

10.30 – 17.30 h (Day 1)  
09.00 – 17.30 h (Day 2)  
09.15 – 12.30 h (Day 3)

## Date:

10<sup>th</sup> MAR 2017 – 12<sup>th</sup> MAR 2017

# TRIALIST 2017 THREE DAY COURSE

 DAY 2		11 <sup>TH</sup> MARCH 2017
06.30 – 09.00	Breakfast	
09.00 – 10.15	Clinical Trial Design: <i>Asthma</i>	(Beier)
10.15 – 10.30	Coffee Break	
10.30 – 12.00	Clinical Trial Design (includes FDA 2016 Guidance): <i>COPD</i>	(Beeh)
12.00 – 12.45	Impact of HTA – de facto 4th Hurdle? <i>European Perspective</i>	(Beeh)
12.45 – 13.45	Lunch	
13.45 – 14.30	“AMNOG” Benefit Assessment in Germany Today and Tomorrow <i>Implications for Trial Design and Experience with Respiratory Drugs</i>	(Beeh)
14.30 – 15.15	Practice Session	(All)
15.15 – 16.15	Practical Case Study: <i>Asthma</i>	(All)
16.15 – 16.30	Afternoon Coffee Break	
16.30 – 17.30	Practical Case Study: <i>COPD</i>	(All)
17.30	Summary and Discussion	(All)
	End of Day 2	
 DAY 3		12 <sup>TH</sup> MARCH 2017
06.30 – 09.00	Breakfast	
09.15 – 10.30	Practical Breakout Session Part 1 (at insaf Research Site) <i>a) Spirometry b) Whole-body plethysmography c) Exercise testing</i>	(All)
10.30 – 10.45	Coffee Break	
10.45 – 12.00	Practical Breakout Sessions (Asthma) <i>a) Airway Challenge Models b) Skin Testing and exhaled NO Monitoring</i>	(All)
12.00 – 12.30	Roundup Summary and Conclusion, Certification	(All)
13.00	Lunch and Departure	

## REGISTRATION:

### Registration via

- masterclass2017@aereon.de
- Fax +49 611 9854348



€ 250  
**EARLY BIRD  
DISCOUNT**  
on registration fee until  
13-JANUARY-2017

---

### Registration form:

I hereby sign up to the 3<sup>rd</sup> "Masterclass Respiratory Trials 2017"

Name/First Name .....

Position/Department .....

Company .....

Street Address .....

City, ZIP Code .....

Country .....

Phone .....

E-Mail .....

Date, Signature .....

---

**Costs: 2950,- EUR (excl. VAT)**

Early Bird Registration Fee 2700,- EUR (excl. VAT) for registrations until 13<sup>th</sup> JAN 2017!

### Package for full 3 days course includes:

- Course registration and learning materials
- Hotel accommodation (Dorint Pallas Wiesbaden) for 2 nights including breakfast
- Lunch Buffet and Coffee break Day 1, Day 2 and Day 3
- Get-together dinner evening Day 1

**Minimum of 5 participants/registrations required, maximum 12 participants.**



Internet: [www.aereon.de](http://www.aereon.de)

Date / Venue: Friday, 10<sup>th</sup> March 2017 – Sunday 12<sup>th</sup> March 2017.

---

#### **Dorint Pallas Hotel Wiesbaden**

Auguste-Viktoria-Str. 15

65185 Wiesbaden

[www.hotel-wiesbaden.dorint.com](http://www.hotel-wiesbaden.dorint.com)

Phone +49 611 3306-0

---

#### **insaf Respiratory Research Institute**

Biebricher Allee 34

65187 Wiesbaden

[www.insaf-wi.de](http://www.insaf-wi.de)

Phone +49 611 9854410

---

#### **Directions:**

Dorint Hotel and insaf Institute are located in the heart of Wiesbaden, the capital of the federal state of Hesse, within walking distance of Wiesbaden central train station and only a 15 minute car ride from **International Airport Frankfurt/Rhine-Main (FRA)**.

---

#### **Terms and Conditions**

Our general terms and conditions apply (as of 01.03.2015), which we will send upon request and can be also be found on [www.aereon.de](http://www.aereon.de).

---

#### **Any enquiries should be directly addressed to:**

Kai M. Beeh, Chairman MasterClass 2017

[k.beeh@aereon.de](mailto:k.beeh@aereon.de)

Phone: +49 611 9854347