

AEREON CONSULTING &  
PHARMA SERVICES

ANNOUNCES THE



# 5<sup>th</sup> MASTERCLASS RESPIRATORY TRIALS

# 2019

Supported by insaf Respiratory Research Institute

Includes  
Recent Trials  
and HTA  
Decisions!

**AEREON**  
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**insaf**  
Respiratory Research Institute

# 5<sup>TH</sup> MASTERCLASS RESPIRATORY TRIALS

## MAR 08-10, 2019

### 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 benefit assessment (AMNOG). Enjoy hands-on practical sessions for respiratory outcome measurement including spirometry, airway challenge, plethysmography, exercise testing, and more.

### WHO SHOULD ATTEND?

Trial Managers, Industry Executives, Scientists, Project Leaders, etc. involved in Pharmacology, Therapeutic Development, Medical Science and Communication, R&D, Market Access / P&R etc. in the Respiratory Indication Area.

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### YOUR SPEAKERS:

Drs. Beier and Beeh sum up experience of over 20 years in respiratory clinical research, with more than 100 trials planned, designed and conducted. They have been involved in hundreds of lectures and educational activities and have published over 150 peer-reviewed articles in the field of Pulmonology. Dr. Beeh holds a degree in Market Access Management from the renowned European Business School (EBS) in Oestrich-Winkel and regularly serves as external advisor for Value Dossier Strategies.



External speaker(s) are renowned international experts in the field of Asthma and COPD.

### **Venue:**

Dorint Pallas Hotel Wiesbaden  
Auguste-Viktoria-Str. 15  
65185 Wiesbaden

### **Time:**

10.30 – 17.30 h (Day 1)  
09.00 – 17.30 h (Day 2)  
09.30 – 12.30 h (Day 3)

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

Date: 08<sup>th</sup> MAR 2019 – 10<sup>th</sup> MAR 2019

# 5<sup>TH</sup> MASTERCLASS RESPIRATORY TRIALS

## MAR 08-10, 2019

### AGENDA 5TH MASTERCLASS RESPIRATORY

DAY 1: 08th MARCH 2019		
10.30 – 10.45	Welcome and Introduction	(All)
10.45 – 11.30	Respiratory Anatomy and Airway Pathology	(Beeh)
11.30 – 13.00	Clinical Methodology in Respiratory Medicine <i>Pulmonary Function Testing, Challenge Models, Airway Monitoring etc.</i>	(Beeh)
<b>13.00 – 14.00 Lunch</b>		
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)
<b>16.15 – 16.30 Afternoon Coffee Break</b>		
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	
<b>19.00 Meeting for Dinner at “Käfer’s Bistro”, Wiesbaden</b>		

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DAY 2: 09th MARCH 2019		
06.30 – 09.00	Breakfast	
09.00 – 10.15	Clinical Trial Design: <i>Asthma (with recent trials examples)</i>	(Beeh)
10.15 – 10.30 Coffee Break		
10.30 – 11.45	Clinical Trial Design (includes FDA 2016 Guidance): <i>COPD (with recent trial examples)</i>	(Beeh)
11.45 – 12.15	Breathing Class	(Beier)
12.15 – 13.00	Impact of HTA – de facto 4th Hurdle? <i>European Perspective</i>	(Beeh)
13.00 – 13.45 Lunch		
13.45 – 14.45	"AMNOG" Benefit Assessment in Germany: <i>Implications for Trial Design and Experience with Respiratory Drugs</i>	(Beeh)
14.45 – 15.30	Group Activity	(All)
15.30 – 17.30	Practical Case Studies in Asthma and COPD	(All)
16.15 – 16.30 Afternoon Coffee Break		
17.30	Summary and Discussion / End of Day 2	(All)

DAY 3 15TH APRIL 2018		
06.30 – 09.00	Breakfast	
09.30 – 12.15	Practical Breakout Sessions (at insaf Research Site) <i>a) Spirometry b) Whole-body plethysmography c) Exercise testing d) airway challenge e)* FOT f)* LCI (*supported by ERT)</i>	(All)
10.30 – 10.45 Coffee Break		
12.15 – 12.30	Roundup Summary and Conclusion, Certification	(All)
12.30 Lunch and Departure		

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## MAR 08-10, 2019

### REGISTRATION:

Register by mail: [Masterclass2019@aereon.de](mailto:Masterclass2019@aereon.de) (or Facsimile to +49 611 9854348)

Registration form:

I hereby sign up to the 5th "Masterclass Respiratory Trials 2019"

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 25th JAN 2019!**

Package for full 3 days course includes:

- Course Registration and learning materials
- Hotel Accomodation (Dorint Pallas Wiesbaden) for 2 nights incl. breakfast
- Lunch Buffet and Coffee break Days 1-3
- Get-together Dinner evening Day 1

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

**Date / Locations: Friday, 08<sup>th</sup> March 2019 - Sunday 11<sup>th</sup> March 2019.**

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### *Venue Hotel:*

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

### *Venue Site:*

insaf Respiratory Research Institute

Biebricher Allee 34 65187 Wiesbaden

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

Phone +49 611 9854410

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### **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).

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### **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 [here](#).

Any enquiries should be directly addressed to:

Kai M. Beeh, Chairman MasterClass 2019

[k.beeh@aereon.de](mailto:k.beeh@aereon.de); Phone: +49 611 9854410