

**AGAH Workshop at  
German Pharm Tox Summit 2019  
Wednesday, 27 February 2019 Stuttgart**



**Introduction to biomarkers and pharmacodynamic models  
and their use in drug development**

The workshop addresses young scientists working in basic pharmacological research and other colleagues involved in biomedical research who would like to know more about early phase clinical development.

Biomarkers and pharmacodynamic models will be the focus of this workshop. Translation from knowledge derived from non-clinical studies to planning and conduct of early clinical trials aims at mitigating risk as well as at increasing the predictability for a safe and successful development. Biomarkers fit for purpose and meaningful pharmacodynamic models are most important tools in this context.

Learn from experts in early medicines development how to assess safety and tolerability, how to investigate mechanisms of action and how to demonstrate proof of concept for promising new compounds in healthy subjects and patients.

Breaks present a good opportunity for networking with faculty and colleagues. The number of participants is limited to 50 persons. Participation fee is 40 Euro for delegates fully registered for the GPTS and 100 Euro for a day ticket for the AGAH Workshop only.

**Programme, 27 February 2019**

**Morning Session**

*Chairs: Barbara Schug, Oberursel; Georg Wensing, Wuppertal*

**09:00**

**Welcome**

*Georg Wensing, Wuppertal*

**09:05-10:45**

**Pharmacodynamic endpoints and inclusion of biomarkers in early clinical trials**

*Jens Rengelshausen, Aachen and Michael Zühlsdorf, Darmstadt*

**10:45-11:45**

**Break for plenary lecture GPTS**

**11:45-12:15**

**Networking lunch break**

**Afternoon session**

*Chairs: Kerstin Breithaupt-Grögler, Frankfurt; Jens Rengelshausen, Aachen*

**12:15-13:00**

**Biomarkers for cardiovascular pharmacodynamic effects -  
may 'digital' biomarkers provide more realistic data than bedside assessments?**

*Frank Kramer, Wuppertal*

**13:00-13:45**

**Challenges in using biomarkers for developing anticoagulants**

*Dagmar Kubitzka, Wuppertal*

**13:45-14:00**

**Break**

**14:00-15:15**

**Safety markers in early phase trials (drug induced renal and liver injury,  
assessment of neurological adverse reactions)**

Introduction to topic: *Frank Donath, Erfurt*; Specific safety markers: *NN*

**15:15-16:00**

**How to evaluate drug effects on the QT(c) interval in healthy subjects and patients**

*Jens Rengelshausen, Aachen*

**16:00-16:15**

**Break**

**16:15-16:45**

**Stratified medicine – development of companion diagnostics**

*Michael Zühlsdorf, Darmstadt*

**16:45-17:00**

**Wrap-up and conclusion**

(15 min)

*Kerstin Breithaupt-Grögler, Frankfurt; Jens Rengelshausen, Aachen*

**17:00**

**End of Workshop**