ORGANISATION

Workshop Fee

400 € Non-Member

300 € Member of AGAH | EUFEMED and DGKliPha or young scientistics until the age of 30 years

100 € Member of Regulatory Agencies and ethics commission

Delegate number is limited to 70 persons.

Final Registration: November 1, 2019

VENUE

GSI - Gustav Stresemann Institut Bonn
Langer Grabenweg 68
53175 Bonn
Web: www.gsi-bonn.de

REGISTRATION

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E-Mail: agah-meetings@csihamburg.de

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Download Anmeldeformblatt PDF

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AGAH
Arbeitsgemeinschaft für angewandte Humanpharmakologie e.V.
Association for Applied Human Pharmacology

AGAH DISKUSSIONSFORUM

HOW TO INTERPRETE AN INVESTIGATOR'S BROCHURE FOR MEANINGFUL RISK ASSESSMENT

NOVEMBER 11, 2019
BONN

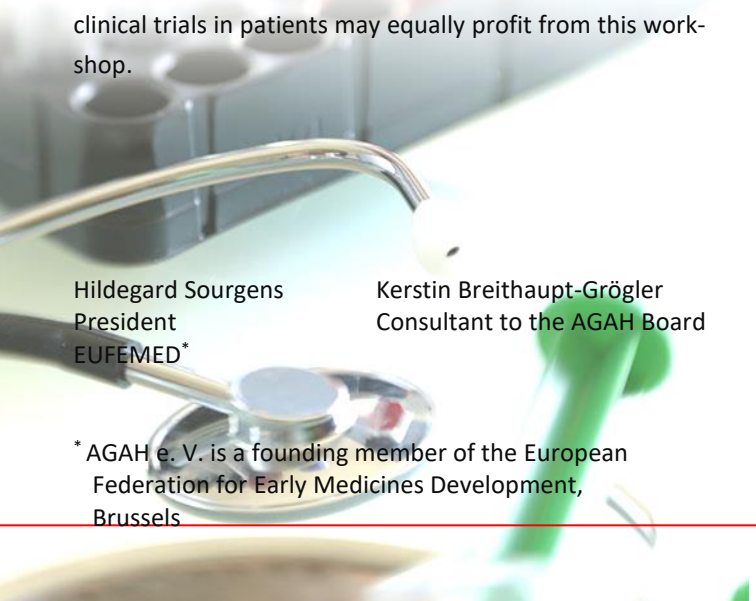
CONTENT

The Investigator's Brochure is the key document for the Sponsor to compile the pertinent knowledge on the pharmaceutical, pharmacological, and toxicological characteristics of and –if any- the clinical experience with the investigational medicinal product (IMP). Critical appraisal of potential safety risks and appropriate precautions on how to avoid putting healthy subjects or patients receiving the IMP at risk is required to provide guidance for the investigator.

In first-in-human and early phase clinical trials, clinical experience with the IMP is lacking or sparse and non-clinical safety assessments must enable an adequate risk assessment to support the transition from animal models to man.

This AGAH discussion forum will debate what is required from an IB to provide proper guidance for the investigator about an IMP in early clinical trials.

The discussion forum addresses investigators and trial teams with some hands-on experience in early phase clinical trials. Clinicians performing first in human trials / early clinical trials in patients may equally profit from this workshop.



Hildegard Sourgens
President
EUFEMED*

Kerstin Breithaupt-Grögler
Consultant to the AGAH Board

* AGAH e. V. is a founding member of the European Federation for Early Medicines Development, Brussels

MORNING SESSION

09:00 Registration

09:00 Welcome and Moderation
K. Breithaupt, Frankfurt/M.
H. Sourgens, München

Online Survey (Who attends this workshop?)

09:10 **The Investigator's Brochure - Key information to support early clinical trials**
J. van Gerven, Leiden/NL

10:00 **Deficiencies / Uncertainties in IBs - The Regulatory Authority's experience**
E. Stahl, Bonn; N N, Langen;
T. Sudhop, Bonn

10:45 Break

11:15 **Guidance for the Investigator**
Chair: *G. Mikus, Heidelberg*

View point of Sponsors
Expectations from Regulatory Agency, Ethics Committee, and Investigator

F. Donath, Erfurt
K. Göhler, Aachen
J. Hasford, München
T. Sudhop, Bonn
G. *Wensing, Wuppertal*

12:15 **Structured Open-Forum Discussion**

- **Online Survey** (Experience of the audience: How to find the relevant safety information in an IB)
  J. Rengelshausen, Aachen
- **Online Survey** (Experience of the audience: Does the IB allow a meaningful risk assessment?)
  K. Göhler, Aachen
- **Questions raised by the Audience**

13:00 Break

AFTERNOON SESSION

13:45 **Reference safety information – a key element of the IB**
K. Erb-Zohar, Hanau

Online Survey (Experience of the audience: Where to find the reference safety information in the IB)
K. Erb-Zohar, Hanau; J. Rengelshausen, Aachen

14:05 **Discussion**
F. Donath, Erfurt
K. Erb-Zohar, Hanau
G. Mikus, Heidelberg
E. Stahl, Bonn
G. *Wensing, Wuppertal*

14:30 **Potential risks for human subjects associated with inadequate non-clinical safety assessment**
S. Plassmann, Basel/CH; L. Wiesner, Bonn

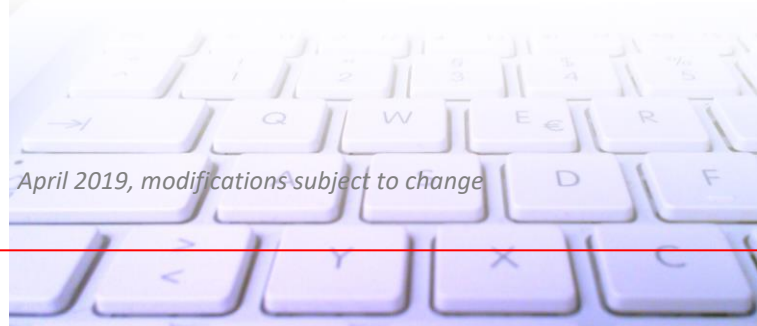
15:00 **Discussion**
S. Plassmann, Basel/CH
J. van Gerven, Leiden/NL
L. Wiesner, Bonn
NN, Langen

15:30 Break

15:45 Case study presented by *J. van Gerven, Leiden*:
Integrating data from the IB – a new tool for translational integration of preclinical effects

16:45 **Wrap-up**

17:00 End of Workshop



April 2019, modifications subject to change