ORGANISATION

Attendance Fee

680 € Non Member

430 € Member of AGAH, EUFEMED or one of the VKliPha-Societies or Junior Scientist up to the age of 30

The participation fee is per person. Please note, according to §4 (22) German turnover tax law, registration and workshop fees are exempt from VAT. Registration fees are charged and collected on behalf of AGAH e.V.

All bookings are subject to change

Registration Deadline: October 31, 2018

Due to a limited number of participants, confirmations will be on a ‚first come first serve' basis.

WORKSHOP VENUE

SocraTec R&D GmbH
Im Setzling 35
61440 Oberursel (Germany)

REGISTRATION

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CONTACT

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Registration form Download (PDF)

CONTENT

Applied Course Biostatistics

You do not necessarily want to become a Biostatistician but you always wanted to understand a bit better the concepts and principles of biostatistics in clinical trials. If this is true, this workshop is the right place for you – and biostatistics is definitely more than randomization and sample size calculation…
This workshop will give an overview on statistically relevant aspects of data structures, principles of descriptive statistics, basic concepts of hypothesis testing, sample size estimation and statistical implications of study designs in Phase I trials. That is, you will learn more about statistical aspects of typical Phase I trials like bioequivalence trials including adaptive design and replicate administrations for highly variable drugs but also First in Human and other dose escalation trials. Thereby you will get a better understanding of the contribution of biostatistics to trial designs and evaluation of clinical data.
This workshop has been developed for investigators, project leaders and other relevantly involved functions in pharmaceutical industry, CROs and hospitals, who are responsible for Clinical Pharmacology trials. But also for scientists at regulatory authorities, ethics committees or universities being involved in early clinical trials this workshop will provide excellent insight into biostatistics and hands-on experience. Practical examples will perfectly complete the scientific presentations. The knowledge and understanding obtained in this course will help you to facilitate the communication with your biostatistical colleagues, in the generation of scientifically sound trial concepts and enable you to evaluate and interpret the obtained clinical data in a professional way.

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

AGAH WORKSHOP

APPLIED COURSE BIOSTATISTICS

Programme

NOVEMBER 7-8, 2018
OBERURSEL (GERMANY)

PROGRAMME · DAY 1 · November 7, 2018

09:00 Registration

10:00 **Welcome and introduction** of participants and speakers
Barbara Schug, Oberursel (Germany)

10:30 **Basic concepts**
An introduction into data exploration of an observed sample using graphical displays and descriptive statistics, i.e., statistical summary measures for location and dispersion and distributions for different types of data.
Gisela Volkers, Aachen (Germany)

11:00 *Coffee break*

11:15 **Statistical inference and confidence intervals**
Description of the goal of statistical inference. Estimation of the population mean from a given sample; Definition and interpretation of confidence intervals.
Guido Thömmes, Aachen (Germany)

12:00 **Exercise 1: basic concepts and statistical inference**

12:30 *Lunch break*

13:30 **Hypothesis testing and sample size calculation**
Presentation of statistical tests, null and alternative hypotheses, Type-1 and Type-2 error, and power. Definition and interpretation of the p-value. How to perform a sample size calculation for a statistical test.
Gisela Volkers, Aachen (Germany)

14:30 **Exercise 2: hypothesis testing and sample size**

15:00 *Coffee break*

15:15 **Trial design concepts**
Presentation of trial design concepts like superiority, non-inferiority, and equivalence trials; Parallel and cross-over designs, dose-escalation designs. How to perform randomization
Gisela Volkers, Aachen (Germany)

15:45 **Statistical analysis of a bioequivalence trial**
Presentation of the statistical model for the 2x2 cross-over design and Bioequivalence range for the alternative hypothesis. How to perform the test of equivalence using the two-one-sided-tests (TOST) procedure. Description of the impact of power and sample size.
Guido Thömmes, Aachen (Germany)

16:45 *Coffee break*

17:00 **Exercise 3: h bioequivalence trial**

17:30 **Discussion**

18:00 End of Day 1

PROGRAMME · DAY 2 · November 8, 2018

08:30 **Wrap-up Day 1**
The most important learnings and any open questions from day 1 will be discussed
Hannes Buchner, München (Germany)

09:00 **Bioequivalence with two-stage sequential Design**
Presentation of the tool of adaptive designs for specific bioequivalence trials with unknown effect size or variability. An introduction into two-stage sequential designs which maintain the overall alpha error while gaining flexibility. Discussion of statistical approaches as well as considerations regarding logistics and guidelines. Presentation and discussion of a case study.
Josef Höfler, München (Germany)

11:00 *Coffee break*

11:15 **Highly variable drugs and bioequivalence assessment**
Presentation of the replicate design approach with comparison of the differences between EU and US requirements; consequences for sample size estimations; risk assessments in case of yet unknown but expected high variability
Josef Höfler, München (Germany)

12:45 **Exercise 4: highly variable drugs**

13:15 *Lunch break*

14:15 **Dose-escalation and first-in-human trials**
Discussion of traditional approaches for dose finding such as 3+3 and placebo-controlled designs and state of the art models as the Bayesian logistic regression model. An introduction of statistical aspects in early clinical development in the light of the new EMA guideline for first-in-human trials will be presented eg. dose leader concept, randomization, dose proportionality.
Hannes Buchner, München (Germany)

16:15 *Coffee break*

16:30 **Discussion**

17:00 End of Course

Faculty

Dr. Hannes Bucher
Staburo GmbH
München (Germany)

Dr. Karin Göhler
Aachen (Germany)

Josef Höfler
Staburo GmbH
München (Germany)

Dr. Barbara Schug
SocraTec R&D GmbH
Oberursel (Germany)

Dr. Guido Thömmes
Grünenthal GmbH
Aachen (Germany)

Gisela Volkers
Grünenthal GmbH
Aachen (Germany)