**Training**

# 3 Statistical principles and methods in medicine

## ■ Training description

The primary objective of this training is the **reading, interpretation and critical assessment of scientific outputs from clinical studies according to ICH guidelines.** Other concepts such as design of phase IV studies, meta-analysis and epidemiology are also included in the training.

## ■ What should you learn?

- Interpret the outputs of statistical analysis – p-values, confidence intervals, Kaplan-Meier ...
- Define and interpret the study objectives
- Present the data in form of tables, graphs and descriptive statistics
- Understand and interpret the clinical outputs – risk ratio, hazard ratio, number needed to treat ...
- Interpret the epidemiological data and health care statistics (WHO, OECD ...)

## ■ Who should participate?

The typical participants are:

- Medical advisors and product managers of pharmaceutical companies
- Doctors writing their PhD studies, involved in clinical research or just seeking the understanding of statistics behind clinical trials
- Governmental and health insurance employees working with outputs from clinical studies

## ■ How can you participate in the training?

- Dedicated training for a pharmaceutical company. Exact length and training content can be modified based on agreement. Typically **the training includes the interpretation of the results from 2 clinical studies of your choice.**
- Sponsored trainings for doctors – must be initiated by the sponsor. Exact length and training content can be modified based on agreement.
- The basic training takes 2 days of approximately 8 hours of training per day. Exact length can be modified based on agreement.

## ■ Trainer

Mgr. Miroslav Helbich, PhD gained his statistical skills as particle physicist working in forefront research organizations such as Desy (Hamburg), Cern (Geneva) or Columbia University (New York). In 2005 he established a private company Caldera s.r.o with the focus on statistical data analysis. Since then he worked on more than hundred phase IV clinical trials, patient registries, cost-effectiveness modeling, seminars, trainings and consultations to a broad spectrum of pharmaceutical companies.

## ■ Contact

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## ■ Training content

### *Study objective definition*

1. Definition of study objectives, output parameters and postulation of hypotheses
2. Study design according to ICH guidelines
3. Patient selection, inclusion and exclusion criteria, randomization
4. Data quality definition

### *Statistical analysis*

5. Data presentation – tables and graphs
6. Descriptive statistics – mean, median, SD etc
7. Measurement errors, bias, confidence intervals
8. Statistical distributions
9. Hypothesis testing, p-values and interpretation of the results
10. Survival analysis and Kaplan-Meier method

### *Interpretation of the results*

11. Interpretation of the results from clinical study, evaluation of impact on patients and clinical praxis (relative risk, risk ratio, hazard ratio, number needed to treat ...)
12. Making conclusions and recommendations for clinical praxis
    Epidemiological data – incidence, mortality, prevalence, survival..

### *Control of the results in clinical praxis*

13. Improtance of phase IV studies and patient registries on monitoring of outcomes in real clinical praxis
14. Epidemiological data – incidence, mortality, prevalence, survival, life expectancy...

The training does not include the explanation and training of the calculation techniques.

## ■ Training methods

The training is executed in interactive form. The **training requires active participation** in solving problems and case studies, discussion and sharing of ideas and experience.