Better Safe than Sorry!

Optimal Planning and Analysis of Your Bio-Studies

Your tasks

<table>
<thead>
<tr>
<th>Question</th>
<th>Objective</th>
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<tbody>
<tr>
<td>Is verum better than placebo?</td>
<td>statistically significant proof of efficacy</td>
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<td>Do my new and my old product have the same effect?</td>
<td>establish bioequivalence</td>
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<td>How many trial animals do I need?</td>
<td>reliable results with a minimum effort</td>
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<td>What's the relation between dose and effect?</td>
<td>quantify the dose-effect-relation, estimate the ED50 value</td>
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<td>Is my toxicological test sensitive enough?</td>
<td>calculate the specificity and sensitivity of the test</td>
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<tr>
<td>Is the work in our labs reliable enough?</td>
<td>estimate the reproducibility of experiments</td>
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Do these questions sound familiar?

Government agencies like the FDA constantly raise the standards on the safety and quality of pharmaceutical and other life science products. Increasingly, national and international organizations cooperate in this area. Likewise, mere drug safety is no longer considered sufficient. More and more often, drug approval requires a proof of efficacy as well.

Today, no life science company can afford to default on a thorough statistical planning and analysis of its trials, bioassays and studies. It is no coincidence that agencies have issued detailed guidelines on these topics. In addition, the early use of modern statistical methods in product development offers the quickest route to high-quality products and serves as a safeguard against recklessly wasted research funds.

AICOS Technologies is your competent partner regarding these issues.

Our strength

- **Scientific expertise in the field of biostatistics**
- **Many years of experience from numerous projects carried out with leading pharmaceutical, agrochemical and cosmetics companies**
- **In-depth knowledge of the most important software packages for experimental design and data analysis**
In close cooperation with you, we will identify the precise nature of the problem and then solve it by using adequate, GLP-conform statistical methods. For data analysis, we use SAS, S-Plus and our Excel-compatible validated software EasyStat. Thanks to our practical experience, we are able to communicate the analysis results and their correct interpretation to the subject matter scientist in non-technical terms.

Our competence

Case-control studies
- comparison of treatment groups
- execution of multiple tests (Dunnett, Tukey etc.)
- parametric and non-parametric analysis of variance

Dose finding studies
- compartmental and non-compartmental analysis
- pharmacokinetic analyses (e.g. Michaelis-Menten kinetics)
- repeated-measurement analysis

Mutagenicity studies
- analysis of micronucleus assays
- assessment of sensitivity and specificity of cytogenetic tests

Bioequivalence and bioavailability
- assessment of individual and population bioequivalence

Experimental design and sample size calculation
- sample size calculation
- post-hoc analyses
- designs for sequential trials

Survival analysis
- Kaplan-Meier estimation
- Cox model analyses

Training

We offer a comprehensive offer of courses in applied statistics. The course are regularly held in English, German and French. For the latest news and dates, please visit our website www.aicos.com. Bioscientists will be particularly interested in the courses Visualization and Analysis of Laboratory Data, Introduction to Biostatistics, Analysis of Repeated Measurements and Introduction to Multivariate Data Analysis.

In addition, we offer in-house courses designed to meet your specific demands. Among others, in-house courses have taken place at the following companies: Aventis Pharma, Ciba Speciality Chemicals, Hoffmann-La Roche, Novartis, Pentapharm, Siegfried, and Syngenta.