BioTeSys GmbH - The basics of substance testing

Esslingen-based BioTeSys GmbH is contracted by its clients to determine the bioactive potential of substances and substance mixtures of foods and dietary supplements. Substances are tested whether or not they have a positive effect on human health using a range of chemical analyses, cell-based tests and clinical trials.

Dr. Jürgen Bernhardt, CEO of BioTeSys, makes it clear that the analyses are aimed at determining whether a particular substance has a positive impact on human health rather than what its therapeutic effect is. "Substances with a therapeutic effect are classified as drugs and must be tested and approved as such," said Bernhardt. That said, it is not always easy to differentiate between drugs and substances that have a positive effect on human health, so decisions need to be made on a case-by-case basis. In some cases, the concentration of a substance and the food pattern of consumers determines whether a given substance is classified as a drug or as a substance with a positive effect on human health. "There are cases where we need to apply complex risk models in order to define a threshold limit below which a substance, substance mixture or specific food item can be classified as a substance with a bioactive potential rather than a drug. Such models also take into account the food patterns of consumers," said Bernhardt.

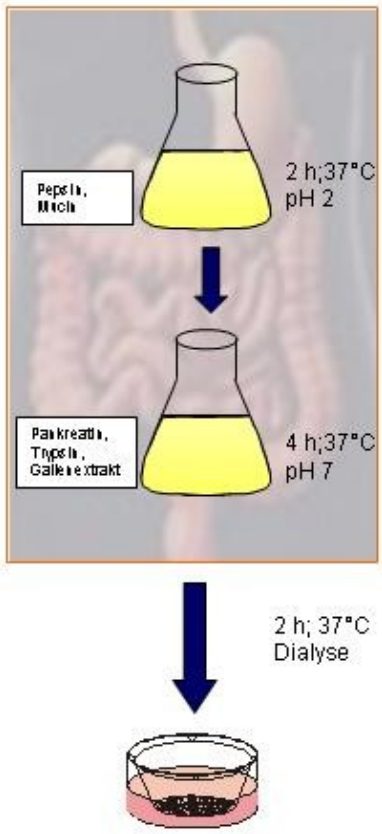
Clinical trials are a key factor in BioTeSys GmbH's assessments. However, it needs to be stressed that the trials carried out by the company to assess the bioactive potential of substances are very different from clinical trials involving pharmaceutical compounds. "First and foremost, we only analyze substances that are clearly classified as food, i.e. substances that also naturally occur in the human body. In addition, our tests involve physiological doses, i.e. substance concentrations that people would take up as part of their normal diet," said Bernhardt. In contrast to traditional clinical trials, BioTeSys GmbH's trials only involve healthy volunteers, and not people who are ill. Volunteers do not necessarily need to be of average weight for their size, they can have a tendency to put on weight, but they must not be adipose; volunteers can also have concentration problems, but not to the extent of such problems being pathological.

Long trials that are designed to find out whether a certain substance has a permanent positive effect on human health are a particular challenge for the Esslingen-based company. It is not always easy to find enough volunteers. "We recruit locals, but, if necessary, we extend our recruitment to the whole of Germany. We are very careful to select the right partners. For example, we ensure that we work with physicians and hospitals that are highly experienced with dealing with the kind of volunteers we need and can help us identify suitable volunteers. We are extremely rigorous when it comes to our recruitment procedures," said Bernhardt.

Dr. Jürgen Bernhardt, CEO of BioTeSys GmbH

Clinical trials are crucial for the correct assessment of the bioactive potential

of substances



In vitro gastrointestinal passage model followed by bioavailability testing.
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Bernhardt and his team organize the clinical trials from beginning to end; this involves determining the design of the trial, allocating the principal investigators and managing the entire procedure, including statistical analysis and final evaluation. The number of volunteers and the duration of trials can vary considerably. A trial might involve between twelve and 400 volunteers and last between three months and two years. "We are currently carrying out four trials and preparing others," said Bernhardt who is of course unable to disclose any details about the studies. It goes without saying that clinical trials must generate as high a quality of evidence as possible. However, the overall evaluation of any given substance also involves data that BioTeSys obtains in two other important fields of competence, i.e. chemical analyses and in-vitro tests. The data thus obtained can support and complement the results of clinical trials and are also used to design the clinical trials. They help BioTeSys to glean information on the bioavailability of a certain substance or on the metabolism of an orally administered compound in the gastrointestinal tract. Substances are exposed to artificial gastrointestinal conditions and subsequently tested in cell-based tests for potential changes in biological parameters. Such systems also provide important information as to whether a substance or a chosen pharmaceutical form is resistant to gastric acid and whether it is released in or before reaching the intestine. Other tests, including chemical and cell-based tests, provide information as to whether a substance has an antioxidative effect, for example whether it is capable of capturing free radicals. BioTeSys also uses cell-based tests for the assessment of biomarkers that are part of the "physiological system involved in creating a feeling of satiety" or provide information about fat

degradation processes. Such substances have the potential to be used for weight control.

A causal chain consisting of chemical analysis, in-vitro tests and clinical trials

BioTeSys covers the entire range of biologically active substances, or as Bernhardt puts it, "substances that can be analyzed with state-of-the-art analytical tools". "We frequently deal with secondary plant substances, including vitamins, carotinoids and minerals. Our clients tell us what issue they want solved and we give them our assessment. In an ideal case scenario, the data from chemical analyses and in-vitro tests provide us with the mechanistic conditions for designing a clinical trial. The three approaches form a causal chain that generates meaningful scientific evidence."

Ex-vivo data obtained in the laboratory also provide BioTeSys with important information. Bernhardt cites one example: "In some clinical trials, blood is withdrawn from volunteers at regular intervals. We then use these blood samples in the laboratory – i.e. ex vivo – to carry out standardized stress tests with cytokines, for example. The results are more informative than in-vitro tests as the supplementation and metabolism of the substance under investigation takes place in an actual human being and is "only" exposed to stress under standardized laboratory conditions. This gives the entire process greater informative value," said Bernhardt.

Standards and standardization are also important for company policy reasons. "On the one hand, the scientific testing of products based on the EU Nutrition and Health Claims Regulation must be carried out at the same level as that required for the testing of pharmaceutically active ingredients. On the other hand, cell-based test methods and experimental conditions must be standardized in order to allow significant data to be acquired and compared," said Bernhardt. BioTeSys is also increasingly using automated in-vitro test systems that enable still greater levels of standardization.

Standardized evidence is in the interest of the food industry

Bernhardt knows from experience that industry is very open to new requirements and possibilities associated with the testing of substances. "Serious manufacturers believe that high testing standards will distinguish them from the industry's black sheep, so such tests are of course in their best interest. However, clinical trials that test the preventive or positive effect of bioactive substance on human health are relatively new and it will take some time to get used to them. It is a new way of looking at things, and it will take a while before it is accepted on a broader basis. However, the ability to scientifically prove a substance's positive effect on human health is seen as a clear advantage. It means that manufacturers can label and advertise their products in an appropriate fashion."

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Article

14-Nov-2011
leh (26.10.2011)
BioRegio STERN

The article is part of the following dossiers

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