The art of designing clinical trials with dietary supplements

Esslingen, 2015-06-02, in order to be assessed by the European Food and Safety Authority (EFSA), claims on effects and efficacy of selected ingredients regarding health require verification and substantiation by clinical trials in vivo. This applies to any kind of biologically active ingredient in food, dietary supplements or functional food. This is certainly easier said than done.

According to the usual practice for pharmaceutical and nutritional studies there are comparable international ethical and scientific quality standards, such as the guidelines set forth by the International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP) and the Declaration of Helsinki regarding the design, conduct and record of a study. But apart from those, there is one special characteristic regarding nutritional trials. This distinction is at the same time the biggest challenge while designing and conducting nutritional trials: food is not medication.

As opposed to drugs, the substances which are supplemented in nutritional trials occur in commercially available food and consequently are present in the human organism and its cells. They tend to act in a network together with a variety of different nutrients and affect multiple cells and organs. Therefore, the requirements caused by the complexity of nutritional trials can only be fulfilled by specialized experts. Beyond that, the expected physiologic effects are small due to quantifying an add-on. Furthermore, the recommended intake is within the physiological range.

That is why the careful selection of relevant endpoints and an appropriate collective of healthy volunteers or–in some cases–volunteers with an increased risk of a special disease is of particular importance. Additionally, accurately defined inclusion and exclusion criteria as well as highly standardized conditions during the conduction of the trial reduce environmental disturbance variables (e.g. age, gender, nutrition) to an unavoidable minimum.

To design a nutritional trial while viewing the problems of testing effects on health in its entirety is the key qualification of specialized experts.

Nutritional CRO & Study site: “Nutrition can be more”

We consider ourselves as a nutritional CRO with profound expertise and longstanding, international experience in nutrition-related questions involving bioactive ingredients. The interdisciplinary team offers valid strategies to cover customer needs. The precise implementation in our in-house testing centre enables the verification of concepts, the detection of health related effects and the scientific substantiation of health claims for market communication. In order to guarantee highest quality, our internal QM system based on ICH-GCP is established.

The aim of our studies is the verification of concepts, the detection of health-related effects to reinforce products and the scientific substantiation of health claims for market communication.

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