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Challenges in clinical nutritional research: How adaptive design can help?

Chow Shein-Chung[2], Tanguy Jérôme[1], Gosoniu Maria Laura[1]
[1]Nestlé Research Center, Switzerland
[2]Duke University School of Medicine, USA

Human studies are essential to obtain evidence of beneficial effects of nutritional interventions on health. Clinical nutritional development plans include a range from small pilot trials to well-designed confirmatory studies, following good clinical practices. Nutrition interventions are generally safe compared to pharmaceutical compounds. Regulatory guidance limits the benefits of nutrition to the maintenance of normal function or the reduction of accepted risk factors. Therefore, nutritional trials do not necessarily follow the same development process as pharmaceutical products. The objectives focus more on maintaining health and preventing risk factors for disease rather than showing efficacy in disease conditions. Clinical trials in the nutritional field have specific challenges to overcome in terms of population, intervention, design and methodology. Additional challenges are the lack of learning phases, small beneficial effects, high heterogeneity of the responses and difficulties in finding appropriate endpoints. In recent years, the use of adaptive design methods in clinical trials has received much attention due to its flexibility and efficiency in clinical development. In practice, adaptive design may provide the opportunity to modify certain aspects of the trial design whilst the study is still ongoing, without violating the quality and the integrity of the data. However, introducing more flexibility may come with many difficulties: major adaptations of on-going trials may result in designs unable to address the original scientific/medical questions. In addition, fundamental differences between pharmaceutical and nutritional research potentially trigger limitations but also opportunities for the application of such innovative design. The aim of this work is to highlight specificities and challenges in nutritional clinical trials, review the concepts of adaptive design and then address the advantages, limitations, and feasibility of commonly considered adaptive designs. Statistical, clinical, operational and regulatory aspects of implementing adaptive designs will be discussed.

sheinchung.chow@duke.edu

New trends within the probiotics market: how producers should deal with them

Daniel R Calvo
Biopolis, Spain

It is undeniable the fact that the probiotic market is suffering a transition where new trends are coming across. In addition to this, regulation (by means of EFSA in Europe) is extremely relevant. New trends and Health Claim Regulations entail new challenges and impact on innovation. Furthermore, the industry is moving at a fast-growing pace so that products containing probiotics are attractive to both food and pharma companies. New indications from different nature -the so called third generation claims- appear more and more as hot topics/niches (atopic dermatitis, psoriasis, stroke, sport nutrition, gut-brain axis), abandoning soft communications such as digestive health or immune system support. In this sense, new and interesting final product ideas are being developed within the industry, where probiotic producers should acquire a relevant role, going together with pharma and food industry based companies as well as contract manufacturers in order to create outstanding synergies and fulfill new market needs.

danielr.calvo@biopolis.es