## Sugar and Spice: Specificities of clinical evaluation of food supplements and herbal products

S. Bianco[1], A. Nunziata[1]

[1]AKROS BioScience Srl, Piazza Aldo Moro 20/d - 00040 Pomezia (Roma)

The clinical evaluation of Food Supplements (FSs) and Herbal Products (HPs) presents specificities that make it different from the clinical evaluation of Medicinal Products (MPs). Among the main factors, the number of components with biological activity on different targets and the clinical expected benefit, which is often the 'well being' or the 'preservation of health status'. This requires specific methodology for the design of the study and the evaluation parameters and end-points to be used.
At the same time, the perception of a FS or HP as 'natural' and therefore 'safe' by definition, requires a careful assessment of the actual safety of FSs and HPs.
Finally, the regulatory requirements for studies on FSs and HPs are different from the ones concerning MPs.
The Author will discuss the methodology and the regulatory requirements of the clinical evaluation of FSs and HPs.