

# **Seminar on Clinical Evaluation / Intervention Studies for New Foods & Food Ingredients**

## ***Current Status and Way Forward***

May 29, 2023, New Delhi

## **Welcome Address By Dr. B. K. Nandi, Chairman, ILSI India**

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**Dear Dr Kanungo, Dr Sesikeran, Madam Rekha Sinha,  
Distinguished Speakers and Participants!**

**A pleasant Good Morning ! And a very warm welcome to all of you** to this important Seminar. This is my first Seminar as Chairman of ILSI India but I have been associated with ILSI India since its inception while I was working for FAO.

**The topic of today's Seminar is very timely..** ILSI India has been discussing this issue in its Scientific Advisory Committee; and K-FFIG (**Knowledge Center on Functional Foods, Immunity and Gut Health**) Governing Council has been deliberating on the need for preparing guidelines for conducting Clinical Evaluation or Intervention Studies for Food and Food Ingredients.. We are aware that the need arises, as with technological advancements besides discovery and designing of new food formats. Now a days many products are available in the markets with various claims about their health benefits for health-conscious consumers. It is recognized that there should be a system for:

- Knowing the quality imparting characteristics of the product,
- How they impact the health,
- What type of claims can be made; and
- How these Claims should be substantiated.

As we are well aware the country has an effective mechanism for conducting Clinical Trials for Drugs under **New Drugs and Clinical Trials Rules, 2019**. In view of the fast progress in food sector it has now become now imperative that guidelines be laid down for conducting clinical evaluation for food and food ingredients including the nutrients.

In this context it is very important to appreciate that there is a fundamental difference between drugs and foods. Drugs are directed toward treatment of diseases. They have specific functions and are generally designed to target single organ or tissues and are not homeostatically controlled by the body. Unlike most drugs, food and nutrients work in complex networks, target all cells and tissues, and thus have multifaceted effects and outcomes. Furthermore, Foods are part of everyday life and food trials are designed closer to “real-life” situations than typical drug trials, which tend to be more highly and more carefully controlled. Therefore, clinical evaluation for food and food ingredients including nutrients must be designed to capture this multifunctionality. I have used the terminologies “Trial and Evaluation” in the context of Food as it needs to be decided which terminology would be more appropriate to be used.

I leave it to the experts in the field, like Dr. Kanungo, Dr Sesikeran, and others who will make Presentations in the Technical Sessions, and Brainstorming Session to debate on the issues, and share their expert views.

**ILSI India's model of work as a tripartite organization** working with national and international scientists, and experts from the public sector, private sector and academia has been unique; and has enabled it to address some of the critical issues in the areas of food safety and nutrition in an efficient and effective manner benefiting public health. We all are aware that ILSI India is a non-profit scientific organization. All its activities follow the Principles of Scientific Integrity.

**During the 25 years of its journey the high quality of scientific information** generated at its Workshops/Seminars, Conferences, Research Programs and Publications have provided guidance to the scientists from Government, Industry and Academia on the actions to be undertaken in their areas of work. Capacity building activities conducted by national and international experts have imparted the necessary skills to the participants. We work with scientists across the Globe through the 10 (ten) ILSI Entities and Headquarters in Washington DC, USA.

**ILSI India has pioneered many activities.** In the area of Nutrition itself it has addressed the issues of eliminating micronutrient malnutrition and conducted research and capacity building activities. The latest being on Vitamin D. These have led to facilitation of fortification in India and South Asian region.

**I would request you to please take a look at Flyer on Pioneering Activities provided in your Folder.**

**Gut microbiome** is an important area of scientific discussions as it is now emerging that it plays an important role in strengthening health and immunity. More and more evidence is coming up that modification of microbiome can help to treat certain neurological disorders and other diseases. Keeping this in view ILSI India has set up the Centre of Excellence called **K-FFIG (Knowledge Center on Functional Foods, Immunity and Gut Health)**. It has a separate Governing Council under the Chairmanship of Dr. B. Sesikeran. Today's Seminar is sponsored by K-FFIG. In its short existence of 3 years K-FFIG has achieved a lot.

Before I conclude I must place on record my deep appreciation for untiring work and guidance provided by Dr. Kanungo and Dr Sesikeran, in organizing today's Seminar, both of whom I respect a lot. They are the best scientists in the areas of both Toxicology and Nutrition and are always willing to share their knowledge and skills. I will be failing in my duties if I do not mention the name of Ms. Rekha Sinha, Executive Director of ILSI South Asian Region for her exemplary contribution in the process of preparing for this Seminar, with these words I would request Dr. Sesikeran to deliver the Key Note Address. He is in the US at present and therefore, will address Online.