Concept Note

Information Brochure

Seminar on

CENFFI

Clinical Evaluation / Intervention Studies for New Foods & Food Ingredients

Current Status and Way Forward

Monday, 29 May, 2023

Inspire Hall, Hotel Le Meridien, New Delhi

ILSI INDIA | K-FFIG

Knowledge Center on Functional Foods, Immunity and Gut Health

International Life Sciences Institute India

CONCEPT NOTE

Food is essential for human life because it is the source of energy and nutrients. Energy supports the activities of human body, whereas nutrients are vital for growth, repair and maintenance of good health. Good nutrition is very important in every stage of life. Pregnant women and lactating mothers require additional nutrients to support a normal pregnancy and lactation for the babies respectively. Infants need energy and nutrients for growth and development, while well-nourished children and adolescents grow and learn better. Young and older adults require different nutrients in balanced amount to maintain good health and prevent diseases.

Further of late there has been greater focus on building health and immunity through food based approaches in recent times. The rising incidence of non-communicable diseases and Covid-19 pandemic – its occurrence and reoccurrence- has further underlined the importance of healthy diet along with appropriate lifestyle.

To fulfill the aspirations of health conscious consumers and with technological advancements a number of new products with a variety of claims have been introduced in the market by the Food Business Operators(FBOs). These are called by various names - Dietary Supplements, Functional Foods or Nutraceuticals.

Food for Specified Health Uses refers to foods containing ingredient with functions for health and officially approved to claim its physiological effects on the human body. It is intended to be consumed for the maintenance / promotion of health or special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol etc. In order to sell a food with specific health claim, data is required in support of their proposed health claims for novel or other non-specified food ingredients/products, the safety assessment of food and effectiveness of functions for health. The claim must be approved by the National regulator (Food Safety and Standards Authority of India - FSSAI in India).

Health claims made by FBOs should be scientifically substantiated, i.e. a cause and effect relationship between a food/constituent (e.g. a nutrient) and a claimed effect has to be established according to generally accepted scientific evidence. Places with health claim regulations, such as the European Union (EU), the USA and Australia/New Zealand, have put in place a scheme for health claims evaluation. The European Food Safety Authority (EFSA) has been mandated to evaluate the validity of health claims made on foods in the EU. Food Safety and Standards Authority of India (FSSAI) has currently no mechanism for providing pre-regulatory clearance/no objection to Food Business Operators for conducting any human intervention studies for generating efficacy and safety data in support of their proposed health claims for novel or other non-specified food ingredients/products for Indian population. This was felt necessary especially by the FBOs in view of the Food Safety and Standards (Approval of non-specified food and food ingredients) Regulations, 2017 and FSS (Advertising and Claims) Regulations, 2018 where studies in Indian population would be important to support their safety and efficacy. The absence of clear guidelines for conducting human intervention studies for food products in India necessitated the consultation among the various stakeholders.

How to Decide Whether a Health Claim is Substantiated?

In order to determine the validity of health claims, two key issues of a health claim need to be examined. Firstly, a health claim shall be clearly defined, which includes the definition and characterization of the food/constituent and the definition of the claimed effect. Secondly, a health claim shall be substantiated by scientific evidence, which must include pertinent human studies. EFSA considers that a cause and effect relationship has not been established, if an unfavorable outcome is obtained from any one of the key questions addressing the claim.

Assessing safety and efficacy against claims is critical to protect consumer's health and wellbeing and generate consumer's confidence. This could be possible only through Clinical intervention evaluation which would help in substantiating claims of health benefits. They would also facilitate product differentiation in the market and allow for their use as products with proven efficacy.

While the country has an effective mechanism for conducting Clinical Trials for Drugs under New Drugs and Clinical Trials Rules, 2019, it is also imperative that guidelines be laid down for conducting similar types of intervention studies *mutatis mutandis* for food and food ingredients including nutrients.

There are some key differences between food and drug trials. Food trials are often designed to evaluate specific marketing claims needing scientific substantiation while drug trials document the safety and efficacy of a specific drug for a specific intended use (e.g., to treat, mitigate or cure a human disease). Food trials tend to be more pragmatic and exploratory as they document human experiences with specific foods in the context of the human diet while drug trials tend to be more explanatory as they document specific drug doses and schedules and specific disease responses.

Food trials typically enroll healthy individuals while drug trials enroll patients with a specific disease type potentially needing the research treatment. Foods are complex mixtures of ingredients (e.g., plant parts, meats, eggs, chemicals, beverages, whole meals, etc.) designed to be palatable and which may have the general health effect under investigation while drugs are highly purified and designed to have a specific effect on a disease.

Health benefits of foods have been evaluated in many ways for hundreds of years and good science was at work even before the first randomized controlled clinical trial (RCT) was ever conducted. From pre-historical times when humans learned to make fire, plant seeds, harvest crops and herd animals, food has been an essential area of human research. Some believe the first clinical trial ever reported was about food. For example, in 1747, Dr. James Lind conducted a systematic clinical experiment using citrus fruits (orange and lemon) to treat scurvy and this work was verified in 1794 when lemon juice and sugar was issued on board the *HMS Suffolk*, a British Navy ship, during a 23-week, non-stop voyage to India which landed without any serious outbreak of scurvy. Prior to this time, scurvy was a leading cause of disease and death among sailors. These types of systematic clinical experiments (i.e., clinical trials) have explored the science of nutrition and food-related health benefits for centuries.

Objectives of the Seminar

The Seminar will look at:

1. Categorization of food health claims and their substantiation.
2. The need for any human intervention evaluation/studies in novel foods.
3. Differences/similarities between clinical trials for drugs and foods.
4. The current approach for conducting human intervention/clinical evaluation in foods in India.
5. Best practices for food clinical intervention studies.
6. Pre-clinical intervention/evaluation activities - Role of FBOs/CROs/Regulators.
7. Clinical intervention/evaluation implementation - Role of FBOs/CROs/Regulators.
8. Post-clinical intervention/evaluation activities - Role of FBOs/CROs/Regulators.

9. The importance of national regulations Food Safety and Standards [*Health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food*] Regulations, 2016 (*Nutraceutical Regulation*) and Food Safety and Standards [*Advertisement and Claims*] Regulations 2018.
10. Modalities for adoption of ICMR ethical guidelines and NDCT CDSO guidelines.
11. Adapting good clinical practices approach and ICMR ethical guidelines to conduct clinical trials for foods.
12. Role of FBO, on his own behalf or on behalf of his/her organization/clinical research organization from private/public sector.
13. The modalities to follow all the principles laid down in the ICMR's 'National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017'.
14. Modalities of periodic adverse event reporting to FSSAI.
15. Decision tree approach.

AGENDA

9.00-9.50 Hrs. **Registration & Tea**

10.00 – 11.00 Hrs. **Opening Session**

Welcome Address
Dr. B. K. Nandi, Chairman, ILSI India

Keynote Address
Dr. B. Sesikeran, Chairman, K-FFIG

Opening Address
Dr. D. Kanungo
Additional Director General, Ministry of Health and Family Welfare, GOI, Retd.

Vote of Thanks
Ms. Rekha Sinha, Executive Director, ILSI India

11.00-11.15 Hrs. TEA BREAK

11.15 – 13.15 Hrs. **Technical Session-I**
Important Considerations for Conducting Clinical Evaluation / Intervention Studies

Chair
Dr. B. K. Nandi & Dr. D. Kanungo

Each Presentation will be for 20 minutes + 5 minutes for Q&A

Introductory Remarks by Chair

Need for Human Intervention Studies in Food and Regulatory Status in the Country and Categorization of Claims and their Substantiation
Dr. Seema Puri, Professor, Department of Food & Nutrition, Institute of Home Economics, University of Delhi, New Delhi

Advertising and Claims Regulation- Need for Appropriate and Adequate Data for Substantiation- Role of ASCI
Ms. Saheli Sinha, General Manager, Complaints and Resolutions, Advertising Standards Council of India, Mumbai

Ethical Conduct of Human Studies-Basis for Good Clinical Practices
Dr. B. Sesikeran, Chairman, K-FFIG

Study Planning, Design, Methodology , Statistical Considerations and Registration Process for Conducting Human Studies

Dr. M. Vishnu Vardhana Rao, Director, ICMR-National Institute of Medical Statistics (retd.), New Delhi

Sum Up by Chair

13.15-13.45 Hrs. LUNCK BREAK

13.45-15.45 Hrs. Technical Session-II
Conducting Clinical Evaluation / Intervention Studies - Role of Stakeholders

Chair :
Major General Dr. Raman Kumar Marwaha
Additional Director, INMAS, DRDO (Retd.)

Each Presentation will be for 20 minutes + 5 minutes for Q&A

Observations by Chair

Pre-Clinical, Clinical and Post-Clinical Studies-Role of Regulators, FBOs and CROs:

Pre-Clinical

Dr. B. Dinesh Kumar, Advisor, Sipra Labs Limited, Hyderabad

Clinical

(also to cover Present Status of Clinical Trials in Drugs and its Proposed Similarities for Food)

Prof. Bikash Medhi, Professor, Department of Pharmacology, Postgraduate Institute of Medical Education & Research (PGIMER) , Chandigarh

Post-Clinical

Dr. Jagadeesh Kodali, Vice President, Vimta Labs, Hyderabad

How to Conduct Systematic Reviews to Generate Supportive Evidence for Content Claims and to Establish Safety

Dr. Pulkit Mathur, Professor and Head, Department of Food & Nutrition and Food Technology, Lady Irwin College, University of Delhi, New Delhi

Sum Up by Chair

15.45-17.30 Hrs. Brainstorming Session : Best Practices for Conducting Clinical Evaluation in Foods & Way Forward

Chair: Dr. D. Kanungo

Introductory Remarks by Chair

Panel of Experts:

Dr. Nandini K. Kumar, President, Forum for Ethics Review Committees in India, Distinguished Scientist Chair, Ministry of Ayush, Former Deputy Director General Sr. Grade (ICMR), Trivandrum

Prof. Renuka Munshi, Professor & Head, Clinical Pharmacology, Nair Hospital, Mumbai

Dr. Seema Puri, Professor, Department of Food & Nutrition, Institute of Home Economics, University of Delhi, New Delhi

Dr. Jagadeesh Kodali, Vice President, Vimta Labs, Hyderabad

Dr. Saurendra Das, Director, Medical, Hazlo Consultancy Pvt. Ltd., Bhubaneswar

Sum Up by Chair

TEA BREAK

Who Should Participate?

The Seminar will be of interest to researchers, scientists and experts from Government; Academia; International Organizations; Industry manufacturing processed foods; food ingredients; functional foods; probiotics and prebiotics, bioactives and nutraceuticals; Health Professionals; NGOs; R&D organizations; CROs and Life Sciences organizations working on Nutrition and Health.

Registration

No registration Fee will be charged from Government, Academic Institutions and Members of K-FFIG Governing Council, however, it is important to register by May 22, 2023.

Registration Fee of INR 3000 will be charged from representatives from Industry from private sector and public sector. Cheque / DD should be drawn in favour of ILSI India and forwarded to Ms. Varsha Bisht along with Registration Form at the following Address: C-39, Ground Floor, Lajpat Nagar III, New Delhi – 110024.

To register use the following link : https://forms.gle/EtmC8WN6ExQDcxjX9

If the Registration Link does not open please copy to the browser or use the enclosed Registration Form.

Registration will be on First Come First Served basis. Registration confirmation will be sent to the participants.

Registration Desk will operate at Conference venue from 09.00 Hrs. onwards on Monday May 29 to handover the Seminar materials

REGISTRATION DEADLINE

Monday May 22, 2023

For any clarification email Mrs. Varsha Bisht at vbisht@ilsi-india.org,
or call her at Tel: 011-41654760 / 29848752 / 29843478

About ILSI India and K-FFIG

ILSI India is an entity of the International Life Sciences Institute (ILSI), headquartered in Washington DC., USA. ILSI India provides scientific inputs and secretariat assistance to the South Asian Region It has headquarters in New Delhi. It is a scientific, non-profit organization and is celebrating 25th Anniversary this year.

ILSI India designs programs to foster multi-sector collaboration for conducting, summarizing, and disseminating science related to most pressing health issues in the region. ILSI strategy encourages global action on identifying and then resolving outstanding scientific questions in the four thematic areas that capture the core of ILSI / ILSI India's work: Food Safety, Risk Science and Toxicology, Nutrition and Health, Sustainable Agriculture and Nutrition Security. They also help elucidate new opportunities for driving scientific progress. All activities follow Principles of Scientific Integrity which are part of ILSI Mandatory Policies. More information can be downloaded from: http://www.ilsi-india.org.

Gut Microbiome is an exciting new field of research. As the science of microbiome and the role of food based approaches in strengthening it over a lifetime is emerging ILSI-India launched Knowledge Center on Functional Foods, Immunity and Gut Health (K-FFIG) - a center of excellence - in New Delhi in October 2019. The Knowledge Center acts as a Think Tank, involving stakeholders from Government, Academia and Industry, that works towards sharing relevant research and technological developments in the area of human microbiome and functional foods. K-FFIG has undertaken several activities including: organization of Scientific Meetings, undertaking Surveys, sponsoring, Research, publishing Monographs and articles in journals, creating Resource Center on latest studies on Microbiome and Gut Health and Functional Foods including Probiotics and Prebiotics. For more information visit: http://www.ilsi-india.org/kffig.htm.

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