SEMINAR on CENFFI

Clinical Evaluation / Intervention Studies for New Foods & Food Ingredients- Current Status and Way Forward

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Compendium of Abstracts & CVs

Sponsored By

Knowledge Center on Functional Foods, Immunity and Gut Health
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Abstracts and CVs

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Opening Session

BRIEF CV

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Dr. Biplab K. Nandi is currently the Chairman of ILSI India.

He served and retired from the Food and Agriculture Organization of the UNITED NATIONS (FAO). He was posted at FAO's Regional Office for Asia and the Pacific, Bangkok, Thailand. He worked as Senior Food Safety and Nutrition Officer for 18 years. There were 46 countries including Pacific Island countries in the Region that Dr. Nandi had to collaborate with in the areas of Food Safety, and Food and Nutrition Security. Besides these Nations, he had vast experience in collaborating with WHO, UNICEF, UNDP, USAID, etc. during his tenure.

Dr. Nandi acquired experience in the field of Food and Nutrition in India as well while he was working as the Technical Adviser for the Government of India.

He is at present closely associated with NIN India, IDA, and other Institutions. He is a distinguished member of the Independent Ethics Committee of the Apollo Multispecialty Hospitals, Kolkata.

He enjoys doing a lot of Philanthropic work in Kolkata and other places. He is the President of an NGO in Kolkata abbreviated as "SNEHA" (Society for Nutrition Education and Health Advancement).

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Dr. Debabrata Kanungo, a medical post graduate (MD), is former Additional Director General, Ministry of Health and Family Welfare Government of India .He is former Expert (Medical Toxicology) and also member expert Medical Toxicology with Central Insecticides Board and Registration Committee, Ministry of Agriculture and Farmers' Welfare, Government of India, He was the Chairman of the Scientific Panel on Residues of Pesticides, the Chairman of Scientific Panel on Contaminants on Food Additives, Flavorings, Processing Aids and Materials in Contacts with Foods; and Member of Scientific Committee under Food Safety and Standards Authority of India (FSSAI). He has 40 years of work experience in regulatory toxicology dealing with human health risk assessment of chemicals including pesticides at National and International level. He received his training in Advance Toxicology from RIVM, The Netherlands. He has received training in Japan on assessment of health hazards due to modernization of Agriculture. He is actively associated with WHO Toxicology Core Assessment Group as an WHO Expert for more than last three decades in preparation of various policy documents for WHO, Environment Health Criteria (EHC) and Concise International Chemical Assessment Documents (CICADs) on Pesticides and Chemicals.

Besides, Dr. Kanungo is a member of WHO expert panel in JMPR (Joint FAO/WHO Meeting on Pesticide Residue) and JECFA (Joint FAO/WHO Expert Committee on Food Additives) since 2006 (Veterinary Drugs & Additive). He was also WHO Expert in FAO/WHO Joint Meeting on Pesticide Specification (JMPS). Dr. Kanungo has led Indian Government Delegations, number of times for CCPR Meetings in various countries. He has received FICCI Award, 2019 for highest contribution in academia in chemical and petrochemical sector He is the Chairman/Member of a number of Past and Present Technical/Advisory Committees of National and International importance viz. Ministry of Health, FSSAI, Tea board of India, etc. Widely travelled throughout the globe to more than 40 countries in his professional capacity. Dr. Kanungo is a regular invited speaker in several meetings related to toxicology and chemical risk assessment both at National and International level.

BRIEF CV

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Dr. B. Sesikeran is Chairman of Governing Council of ILSI India Knowledge Center on Functional Foods, Immunity and Gut Health (K-FFIG) – a center of excellence launched in 2020. He was the Director of National Institute of Nutrition (NIN) Indian Council of Medical Research Hyderabad till 2012. A medical Pathologist by training, he was with the National Institute of Nutrition since 1977. The major area of research has been in Nutritional Pathology particularly in understanding the role of nutrients in cancer prevention. Food safety and toxicology studies were initiated and a pre clinical safety study group was set up in 1998 which has now become one of the leading toxicology facilities in the public sector. During the six and a half years tenure as a Director the Recommended Dietary Allowances for Indians (RDA) along with Dietary Guidelines was revised and the food composition data base project was initiated to update the Nutritive Value of Indian Foods data.

His other responsibilities included Chairman of Food Labeling Committee of the Food Safety and Standards Authority of India (FSSAI), and Chairman of the Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology. Published a little over 100 research papers, and chapters in 5 books. Developed guidelines for GM safety testing, Food Labeling (draft form), Guidelines for Probiotics in Foods and Guidelines for Similar Biologics. Initiated the two years Masters Course in Applied Nutrition at NIN. Despite research and Administrative responsibilities, teaching is the main passion. Post retirement assignments are many but the role as Visiting Faculty teaching Nutrition in the Department of Health Psychology at the Hyderabad Central University is the most relevant. He is a fellow of the National Academy of Medical Sciences and the Andhra Pradesh Academy of Sciences. He was President of Nutrition Society of India and Chairman of the National Committee of the International Union of Nutrition Sciences (IUNS) in the Indian National Science Academy (INSA).

Keynote Address

Clinical Studies with Food or Ingredients as Test Material

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ABSTRACT

Clinical studies for drugs are well standardized and regulated but not for foods or food ingredients. International regulations exist for food ingredients as well as novel foods. Other foods like supplements or traditional foods do not undergo any clinical testing unless the manufacturer plans to make a product specific claim. In India clinical studies may be required for a novel food or ingredient with adequate pre-clinical data for regulatory approval or a novel food or ingredient with history of safe use over 30 years but in another country. A novel food or ingredient with evidence of safety and efficacy mentioned in traditional literature but may not be applicable or the Food Business Operator (FBO) plans to make a product claim or for and efficacy claim particularly in FSDU or FSMP categories.

There should be a mechanism for oversight when FBO plans to conduct a study or submits the data or stakes a product claim. Legally it will be under the purview of the FSSAI. Presently no such norms are available. USFDA or EFSA or FSANZ provide guidance in other countries. At the moment FSSAI or ASCI seek data to substantiate claims.

Prerequisites for the conduct of human studies would be

- An independent clinical research organization with no conflict of interest.
- Skilled and experienced investigators and GLP accredited labs.
- If ICH methods and accreditations are possible then data will be acceptable in OECD countries.
- Must follow ICMR ethical guidelines and conduct the study according to Good Clinical Practices.
- Study design should be appropriate to the outcome with a rationale or justification for doing a human study. Participant safety and voluntariness is important and all studies should be approved by the respective ethics committees and should be monitored.
- Very often studies are carried out by the FBO with good intention but with flawed design, inadequate sample or improper statistics. Since investments would be considerable it would be beneficial to them as well as the regulator and the consumer if there is a proper guideline and expert advice and oversight from the FSSAI.

Technical Session-I

Important Considerations for Conducting Clinical Evaluation / Intervention Studies

Abstracts & CVs

BRIEF CV

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Dr. Seema Puri, PhD has over 35 years of teaching and research experience with interest in infant and young child nutrition, childhood obesity and NCDs, bone health and geriatric nutrition.

She has guided the research of over 55 postgraduate and 17 doctoral students. She has undertaken several research projects funded by World Bank, UNICEF, WHO, University of Sydney, DST, ICMR and others. She has presented her work at several international conferences and has been an invited speaker at innumerable National and International meetings.

She has been awarded several fellowships including the Australian Awards Fellowship, CCGHR fellowship, to undertake specialized trainings abroad. She has been conferred the Distinguished Services Award by the Geriatric Society of India in 2010 and for her significant contribution to Nutrition and Dietetics in 2014. She was felicitated with the Rajamal P Devadas Award 2020 by Nutrition Society of India for her outstanding contribution to applied nutrition. She also is a recipient of the Nutrition Leadership Excellence Award by NIFTEM and Ministry of Food Processing in 2022.

She has published extensively with over 110 publications and nearly 3500 citations. Publications to her credit include a popular “Textbook of Nutrition and Dietetics", an edited book on "Diet and Ageing" and on “Children in India: Opportunities and Challenges”.

Dr Seema Puri has been a short term consultant for UNICEF, WHO (SEARO), WHO (EMRO), FAO and UN World Food Programme. She has been on several important national and international committees, project review groups and task forces including those at FSSAI, Ministry of Health, DST, ICMR and Government of Delhi. Presently, at FSSAI, she is member of the Scientific Panel on Functional Foods, Nutraceuticals, Dietetic and other similar products. She has been involved in the planning of the Midday Meal Scheme and ICDS supplementary feeding programme of the Delhi Government.

She is a member of several other academic bodies including the South Asian Infant Feeding Research Network (SAIFRN), Home Science Association of India and Indian Academy of Geriatrics. She was the National Vice President of Indian Dietetic Association, Executive Council member of Nutrition Society of India and India’s Representative on the Asian Federation of Dietetic Associations. She is also the India representative on the International Federation of Home Economics.

Need for Human Intervention Studies in Food and Regulatory Status in the Country and Categorization of Claims and their Substantiation

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ABSTRACT

The COVID Pandemic along with the rapidly increasing prevalence of non-communicable diseases in India, has brought an increased focus on the importance of a healthy diet and lifestyle. A wide variety of health and dietary supplements are now available in the market claiming to address health concerns like diabetes, hyperlipidemia, bone health and immunity. In order to sell a food with a specific health claim, data is required to support the claim for novel or other non-specified food ingredients/products, the effectiveness of functions for health and the safety assessment of foods. These have to be approved by FSSAI. , which require evidence, scientifically substantiating the claim made. Currently, there are no guidelines in India for conducting human intervention studies for food products to generate efficacy and safety data. It is thus imperative to establish procedures for conducting such trials in India so that the evidence generated will help to authenticate the claims made.

BRIEF CV

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Dr. Saheli Sinha is the General Manager of Complaints and Resolutions and oversees the critical complaints resolution mechanism at ASCI. Under her leadership, ASCI has taken several initiatives in the area of digital tracking, and the development of a new, agile, complaint management system. She also leads ASCI's training and education initiatives for key stakeholders, including corporates and students. Prior to ASCI she has been a Research Insights and Brand Strategy Consultant with over 17 years of experience across Academia and Management Consulting.

Dr. Saheli has a PhD in Sociology from Jawaharlal Nehru University, New Delhi and has worked across academia and industry, which has helped her understand culture, society and people better, equipping her with a richer understanding of human response to various thoughts, including brands and advertising.

Advertising and Claims Regulation – Need for Appropriate and Adequate Data for Substantiation – Role of ASCI

Dr. Saheli Sinha
General Manager
The Advertising Standards Council of India, Mumbai

ABSTRACT

Today an average urban/semi-urban Indian is exposed to about 5000 ads per day. Advertising is not new a concept, but the formats, the medium through which ads reach consumers today are going through significant transitions. The growth of the digital medium has led to proliferation of new age brands, host of new products with lofty advertising claims that are alluring consumers and driving consumption. It is needless to say that a lot of these claims often appear to be misleading at a glance but the manner in which communications and products are packaged, consumers are tricked to believe in them and later left disheartened or disappointed.

The Advertising Standards Council of India has been dedicatedly working at keeping the advertising landscape clean and responsible with a view to safeguarding consumer interest. At ASCI in the last couple of years we have seen a rise in the overall number of ads processed for potential violation under the F&B sector. FY 22-23 witnessed a 110% rise in cases as compared to the previous year. Health & Nutrition claims have been on the rise thanks to the pandemic and with the explosion of brands in the nutraceutical category. 47% of the total ads processed under F&B last year were from brands that sell health and nutrition products. 98% of these were found to be in violation of the advertising code.

This talk aims to cover a brief understanding of ASCI and its process, how complaints against ads from this sector are reviewed, what is permissible – what is not, the nature of data required to substantiate various kinds of claims. As a self-regulator ASCI works within the legal/regulatory framework. The presentation will also touch upon few regulatory requirements for advertising and packaging. The talk would touch upon some other critical issues with respect to claims for e.g. trademarks that appear as claims and how they are evaluated from a consumer point of view.

Ethical Conduct of Human Studies

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ABSTRACT

Across the world Good Clinical Practices as laid down by the ICH guidelines and other regulatory bodies form the basis for conduct of human studies. In India the guidance is based on the ICMR National ethical guidelines for biomedical and health research involving human participants. These guidelines apply to all studies independent of whether it is a food, drug, device or even a software or artificial intelligence used on humans. They also apply to research studies that are non-regulatory in nature. These guidelines have evolved over the last three decades in India and currently implemented effectively. All clinical trials or clinical studies are registered in the Clinical Trials registry of India.

While conducting the best of human trials the most important element will be the safety of the participant. They may be healthy volunteers or patients, Adults or children, men or women , these principles apply to all. The immediate oversight will be by the respective institutional or independent ethics committees. All studies will be conducted by trained healthcare professionals and if the food were to be based on traditional knowledge then it should be conducted by a traditional medicine professional.

There are about a dozen basic principles in the guidelines and each one of these principles would apply independent of the nature of the study. The participants safety, their right, transparency, compensation of their time, confidentiality, doing no harm etc. are some of these principles and the investigators, and ethics committees should ensure that these are followed and properly monitored and adequately documented. Regulatory bodies will approve or consider acceptance of data only if the ethics committees have approved them. Even publication or presentation of data generated out of a human study requires ethical approvals prior to conduct of the study.

BRIEF CV

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Dr. M. Vishnu Vardhana Rao is the Director of the ICMR-National Institute of Medical Statistics (NIMS) and HOD, AI cell, Indian Council of Medical Research, New Delhi. He is a trained mathematical statistician and data scientist. He has a Masters and PhD in Statistics and M.Tech (IT). Dr Rao's has over three decades of experience in planning, executing and analyzing data for several large scale community and clinical based research studies in the domain of nutrition and health. His research focuses on the development and application of innovative and appropriate statistical methods for analysis of large and complex data. His work also encompasses several evidence based and policy relevant research studies.

He was also an administrator for Clinical Trial Registry India (CTRI) is a free and online public record system for registration of clinical trials being conducted in India which has been made mandatory by the Drugs Controller General (India) (DCGI). He served as an International consultant for UNICEF. He has more than 140 papers published in national and international journals and 20 reports to his credit. He guided several post graduates towards obtaining PhD degree in the areas of Multivariate data Analysis, Meta-Analysis and statistical methods in AI & Big data analytics. He is the fellow of FSMS and chief editor Demography India. He is the chief editor of Demographic India and recipient of NAMS oration award, Fellow of Indian society for medical statistics(FSMS), fellow of Telangana Academy of Sciences (FTAS)

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

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ABSTRACT

To undertake any study initially we should have research question of objective, what is the hypothesis we are testing. The next important step is considering an appropriate study design.

Clinical research is classified into experimental and observational studies. The experimental studies are further classified into randomized and non-randomized trials. The observational studies are divided into analytical studies where a comparative group presents or descriptive studies. The analytical studies are cohort studies, case control studies or cross sectional studies.

The frequently used study designs are parallel designs, where the subjects are randomized to the treatment group or control group and follow up and determine the effect of each group. Crossover designs randomizes subjects to different subjects to different treatments but all subjects get all treatments in varying order, the subject is his/her own treatment. Cluster randomization trials are conducted when group of subjects are randomized instead of individual. The reporting guidelines e.g., CONSORT for RCTs, STROBE for observational studies may be followed for reporting and dissemination. It has to be ensured that the study adheres to the ethical guidelines.

Calculation of appropriate sample size plays an important role to ensure that there are enough subjects to provide accurate and reliable assessment with certain statistical assurance. For calculation of sample size the points to be considered are the expected outcome and how large the study should be so that study will have enough power to detect the clinically meaningful differences. It should be noted that valid sample size are calculated under valid statistical *hypothesis and under appropriate study design. Clinical trials are further divided into superiority to demonstrate improved efficacy, equivalence to demonstrate both treatments achieve similar reduction of the evens and noninferiority trial to demonstrate the average efficacy of new treatment is in the predefined range*.

The appropriate statistical tests based on the design of the study and aligning with hypothesis have to be chosen. The commonly used tests e.g. t-test, chi-square, ANOVA, for survival analysis, Kaplan-Meier and regression models e.g. linear regression, logistic regression or cox proportional hazard models maybe applied wherever they are applicable.

In the 59th General Assembly of the World Medical Association, 2008, in its revision of the Declaration of Helsinki among other modifications, specified that: "*Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject". Therefore, all the trials- observational or interventional- should be registered in their respective mandated clinical trial registry portals before initiation of the study. All the trial in India may be registered with Clinical Trials Registry India (CTRI) which is hosted at ICMR-NIMS New Delhi.*

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Technical Session-II

Conducting Clinical Evaluation/Intervention Studies- Role of Stakeholders

Abstracts & CVs

BRIEF CV

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Dr. B. Dinesh Kumar a Scientist in Nutritional Pharmacology and Toxicology served at the ICMR-National Institute of Nutrition around 4 decades. He is instrumental in successfully implementing Public Private Partnership (PPP) programmes and contributed to strengthen the regulatory guidelines & Pre-Clinical Drug Discovery in India. His contributions in Nutrition-Pollution Interaction and Social Drug Epidemiology are added achievements. He has also been actively involved as one of the main investigators in epidemiological outbreaks and as a frontline warrior in COVID-19 operations of ICMR-NIN. He coordinated with IAEA, WHO, World Bank, Indo-US Research Initiative and several National agencies like DBT, CSIR, ICMR, ICAR, DST, AYUSH-CCRAS, MoH&FW, India and UK India (MSDE) and many Private Agencies for scientific projects.

He is Fellow Norman Borlaug, National Academy of Medical Sciences and Andhra Pradesh Academy of Sciences. He has over 80 scientific publications; Regulatory Reports (70); has written several Chapters in books and Popular articles. He has also produced Educational films, guided 17 Doctoral students and has been invited as a speaker, resource person. He is Expert Member in various regulatory and scientific bodies viz., CDCSCO, FSSAI, DCGI, AYUSH, ICAR, BIS, DBT, DST MoEF, MoH&FW for reviewing products / developing guidelines. He was an Expert Member of High Power Committee of ICMR for COVID –Vaccine and Drug Development. He organized several international, national conferences and brainstorming sessions.

Currently Member of Expert Committee FSSAI : Expert Committee for approval of 'Non-Specified Food and Food Ingredients', Scientific Panel on Food Additives', Working committee 'Review of Flavours and Additives'. Expert Working Group of Indian Pharmacopoeia Commission on Vitamins, Minerals, Amino Acids, Fatty Acids etc. and Packaging Material. Expert Committee ICMR on ' Safety of Menstrual products in India'. He is Expert Reviewer in Indian Knowledge system-AICTE. He is resource person and scientific Advisor to Academic, Research , Food and Pharma Institutes / Industry.

Pre-Clinical Studies – Role of Regulators, FBOs and CROs Studies

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ABSTRACT

It is well known that the primary goal of pre-clinical safety evaluation is: 1) to identify an initial safe dose and subsequent dose escalation schemes in humans; 2) to identify potential target organs for toxicity and for the study of whether such toxicity is reversible; and 3) to identify safety parameters for clinical monitoring.

In 21st Century, the Pharma industry is exploring the possibilities of developing newer formulations viz., Nutraceuticals, Functional Foods, Dietary Supplements, Herbals, Botanicals as preventive / therapeutic potential preparation have further changed the consumer concern from the expensive synthetic High-tech modern pharmaceuticals. This led to growing concern among the public, scientists, academia and regulatory agencies on guidelines for safety evaluation of such newer categories of products developed.

The history of development of guidelines for pre-clinical safety/efficacy evaluation of Pharmaceuticals is just a century old concept and well defined by National and international agencies. In the recent past global efforts are continuing to evolve safety (toxicology) guidelines for various category of Foods Products. Japan (1991) introduced Foods for Specific Health Use (FOSHU) system to evaluate health claims. The Dietary Supplement Health and Education Act (DSHEA-1994) of US-FDA don't need to register or approve Food supplements but with restriction on post-marketing report on adverse reaction monitoring. In the current context, they allow 'qualified health claims' with hardly any evidence, as long as a disclaimer is included. The poor implementation of complex, fragmented guidelines in the EU, is now proposing to enforce seven years of exclusivity for truly novel claims to be backed up by solid data on food supplements.

The Ministry of Health and Family Welfare in India has issued Gazette (F. No. 12/PA Regulation/Dir (PA)/FSSAI-2016), Food Safety and Standards Regulation (FSSR), which is now modified (FSSAI-Nutra) Regulations, 2022) for effective implementation from April 2022 with clarity on different category for claim and label claims. In this one of the recommendations for 'novel foods and new ingredients' are approvable subject to submission of historical data on consumption with safety. In case of non-compliance to this, the preclinical studies and clinical trial data can be submitted in consonance to ICMR /NDCT guidelines for approval.

It is known that "Foods or bioactive ingredients in foods that protect or promote health whether they are delivered in raw agricultural commodities, processed foods, dietary supplements, extract beverages or other products marketed directly to consumers. Therefore, safety and efficacy claims have to be certified by the regulators on scientific merits.

The role of FBO/CRO in extending the services from bench to bedside for pharmaceutical preparations is well established. However similar services for Food products / Nutraceutical are challenging specially in designing the protocol & conducting of experiment under regulatory domain for varied categories. In addition, cost effectiveness of such services may also be of concern.

The consumption of food-based products by general population and medical providers is rapidly increasing as potential Health promoters with major Economical contributor. This is a real summon to the regulators in evolving process to conclude safety from preclinical to Clinical data.

BRIEF CV

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Prof. Bikas Medhi is Professor Department of Pharmacology, PGIMER, Chandigarh. He is Ex-Additional Medical Superintendent and Founder of Experimental Pharmacology and Neurobehavioral laboratory as also Coordinator PGIMER Pharmacovigilance and Materiovigilance Centre. He is Regional Coordinator, NADA (North Zone), Ministry of Youth and Sports, Government of India. Co-Convener India Initiate Programme, Lead GCP, GLP, NABH, CPCSEA, NMC Assessor. He is ex Secretary Clinical Pharmacology of Indian Pharmacology Society.

His area of expertise is Experimental Pharmacology, Clinical Research, Regulatory Pharmacology, Development of nano-formulations, Pharmacogenetics, Pharmacogenomics and Stem cells etc.

Prof. Medhi has been dedicated in 2% scientist across the world conducted by Elsevier & Stanford University. He is member executive committee of IUPHAR for Global coverage IUPHAR activities in coordination with WHO (2023-2026). He is also a Member of Codex Committee, USA, DSMB members for several multinational trials.

Prof. Medhi He has published 5 books and more than 500 research papers. He is Editor-In-Chief, Indian Journal of Pharmacology, Editor-In-Chief, International Journal of Pharmaceutical Sciences and Nanotechnology (IJPSN) and PGIMER Drug Bulletin. He has also received several Awards including: Dr. D N Prasad memorial award with Gold medal (ICMR), New Delhi; Dr. V K Bhargava Award with Gold medal (NAMS) ; Dr. B N. Ghosh and Col. Ram Nath Chopra Oration, PK Kar oration from Indian Pharmacological Society (IPS), and VAIDA AWARD 2023.

Clinical Studies-Role of Regulators, FBOs and CROs

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ABSTRACT

Clinical studies play a crucial role in ensuring the safety and efficacy of new drugs and food products. The successful conduct of these trials is a collaborative effort involving regulatory agencies, food business operators (FBOs), and contract research organizations (CROs).

Clinical trials in drugs are governed by strict regulations to ensure patient safety and the efficacy of the products. Regulatory agencies, such as the Food and Drug Administration (FDA) in the United States and the Central Drugs Standard Control Organization (CDSCO) in India, play a vital role in setting guidelines and monitoring clinical trials. These agencies are responsible for approving clinical trial protocols, ensuring adherence to good clinical practice (GCP) guidelines, and evaluating trial results. They review and approve trial protocols, monitor study conduct, and evaluate the safety and efficacy of investigational products.

Food business operators (FBOs) are responsible for complying with regulatory requirements and ensuring that their products are safe and of high quality. FBOs, including pharmaceutical and food companies, are responsible for developing and testing new products in accordance with regulatory requirements. This is particularly relevant for functional foods and nutraceuticals, which may have therapeutic benefits similar to drugs. They collaborate with CROs to design, implement, and manage clinical studies, leveraging the specialized expertise of CROs in areas such as data management, statistical analysis, and regulatory compliance.

Contract research organizations (CROs) provide essential support and expertise in conducting clinical trials, helping FBOs and pharmaceutical companies navigate complex regulatory landscapes. CROs offer various services, including trial design, patient recruitment, data management, and statistical analysis. The use of CROs can improve efficiency and reduce costs for companies conducting clinical trials.

In recent years, there has been a shift towards a more streamlined and efficient approach to conducting clinical trials, facilitated by the adoption of new technologies, such as electronic data capture and remote monitoring. The food industry is progressively adopting similar approaches in response to the increasing demand for evidence-based functional foods and nutraceuticals.

The current landscape of drug clinical trials is characterized by a growing emphasis on personalized medicine, increasing complexity of study designs, and a shift towards decentralized trials. Recent advances in genomics, proteomics, and metabolomics have facilitated the development of targeted therapies tailored to individual patients, resulting in improved outcomes and reduced side effects.

Similar trends are emerging in food clinical trials, as the concept of personalized nutrition gains attraction. As with drug trials, the focus in food trials is shifting towards understanding the unique nutritional needs of individuals and developing products that cater to these

requirements. This shift necessitates the development of robust methodologies, biomarkers, and endpoints for evaluating the safety and efficacy of novel food products.

In conclusion, the successful conduct of clinical trials in drugs and food relies on the collaborative efforts of regulatory agencies, FBOs, and CROs.

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Dr. Jagadeesh Kodali is the Head of VIMTA's Food Division since 2016. He has close to 24 years of experience in Business operations, Laboratory management, Analytical research and testing industry. He gained immense experience in the export requirements with respect to the testing of various Food & Agri commodities. He started his career in VIMTA as Trainee Scientist in 1999 and spent over 6 years handling pesticide residues and toxins analysis in Food, Agri and Beverages. Further he worked for several MNCs in India & abroad in Analytical Research and Testing Field at Senior Manager levels. Before his second stint at VIMTA, Dr. Kodali was Head-Lab Operations for INTERTEK India Food Services. During his career he mastered chromatographic techniques (HPLC & GC), mass spectrometry (LC-MS / MS, GC-MS / MS, Time of Flight and Magnetic Sector HR-MS), Spectroscopy & Spectrometry (AAS & ICP-MS). He holds a Master of Science in Chemistry degree from JNTU, Hyderabad, India and a Ph.D. degree in Chemistry from BITS-Pilani, Hyderabad, India. He serves in several committees of FSSAI (Standard Food testing lab committee, Referral Food testing lab committee, Testing Fee committee, Committee on Improving Efficiency of food testing labs) and committees of BIS (Testing & Calibration advisory committee, FAD28: Test methods for Food products, FAD 27: Pesticide Residues Analysis, FAD 19: Dairy products and equipment, SSD14: SSD-II 14-Drinking Water Supply, Waste Water & Storm Water System Services Committee) as a member. To his credit, he successfully conducted FSSAI's National Milk Quality Survey (NMQS-2018) as project head and contributed for the establishment of National Food Laboratory, JNPT-Navi Mumbai under PPP mode with FSSAI, Govt. of India. He is a qualified Food Analyst as well from FSSAI.

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

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ABSTRACT

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Dr. Pulkit Mathur has done B.Sc. (Hons.) Home Science and M.Sc. Food and Nutrition from Lady Irwin College, and is a gold medallist from University of Delhi. She did her Ph.D. from Faculty of Science, University of Delhi with the research work carried out at the ICMR-National Institute of Nutrition, Hyderabad. In 2005 she joined Lady Irwin College as Assistant Professor, Department of Food and Nutrition.

Dr. Mathur's areas of research interest are food safety and nutrition. She has guided research work on estimating dietary exposure to food additives and assessing the risk posed as also development of strategies to communicate healthy food choices to the general public. She has undertaken several research projects and was co- investigator for a project on spreading nutrition awareness and inculcating healthy food choices among students in Delhi schools. She has published 8 books and more than 85 articles/ chapters in national and international journals/ books/ conference proceedings and periodicals. She has received several awards including Certificate of Merit in recognition of contribution and continued work as a leader in strengthening of the food safety eco-system by the Food Safety and Standards Authority of India. She has guided more than 33 MSc and PhD Scholars. She is a life member of several professional bodies concerned with Food and Nutrition. She is currently National Executive Committee Member of the Nutrition Society of India, Member of the National Committee of the International Union of Nutritional Sciences, and a National Resource Person for the FoSTaC program of FSSAI and National Technical Trainer, Rashtriya Kishor Swasthya Karyakram, MoHFW.

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

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ABSTRACT

Evidence based decision making is important for evaluating claims, assessing safety, and setting regulations for new foods/ingredients. The last decade has witnessed increased recognition of the value of literature reviews for advancing understanding and decision making. This has been accompanied by an expansion in the range of methodological approaches and types of review. There is an emphasis on specification of methods for information retrieval as well as grading of quality of evidence. Hence, Systematic reviews and meta-analyses are preferred to traditional reviews. Systematic reviews follow procedures that are designed to minimise bias by transparent reporting. Meta-analysis is a technique that statistically combines the results of quantitative studies to provide a more precise effect of the results. Cochrane Reviews are systematic summaries of evidence of the effects of healthcare interventions. They are intended to help people make practical decisions. For a review to be called a 'Cochrane Review' it must be in CDSR (Cochrane Database of Systematic Reviews) or CMR (Cochrane Methodology Register).

To conduct Systematic reviews the PRISMA guidelines are generally followed. The PRISMA i.e. Preferred Reporting Items for Systematic reviews and Meta-Analyses statement was first published in 2009. It was later revised in 2020. It includes new reporting guidance that reflects advances in methods to identify, select, appraise, and synthesise studies. The 2020 PRISMA statement consists of a 27-item checklist and a 4-phase flow diagram. To ensure a systematic review is valuable to users, authors should prepare a transparent, complete, and accurate account of why the review was done, what they did, and what they found.

After individual article evaluation, the overall body of evidence with respect to each outcome is determined based on precepts outlined by the Grades of Recommendation Assessment, Development and Evaluation (GRADE) Working Group and recommendations made by the Agency for Healthcare Research and Quality (AHRQ). The GRADE system rates the quality or certainty of the evidence, and Summary of findings (SoF) tables present the results (together with the GRADE rating) for the most important outcomes in the review. Level of evidence ratings for Cochrane reviews and other systematic reviews are assigned a baseline score of HIGH if RCTs were used and, LOW if observational studies were used. The rating can be upgraded or downgraded based on adherence to the core criteria for methods, qualitative, and quantitative analyses for systematic reviews. At least two review authors should work independently to assess the quality of evidence and resolve disagreements. The process for reaching consensus where there are disagreements in ratings should be outlined in the Protocol.

Tangible processes required in completing a review, namely search, appraisal, synthesis, and analysis, are embodied in the SALSA framework. Frameworks like PICO (Patient/ Population, Intervention, Comparison, Outcome) and PEO (Population, Exposure, Outcome) are also widely used in health research to help identify the key concepts of a topic and structure the literature review.

Hence it is the explicit and systematic approach that distinguishes systematic reviews from traditional reviews and commentaries. With increasing focus on generating guidance and recommendations for practice or regulations through systematic reviews, nutrition, healthcare and food safety professionals need to understand the principles of preparing such reviews.

Brainstorming Session

Best Practices for Conducting Clinical Evaluation in Foods & Way Forward

CVs

BRIEF CV

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Dr. Nandini K. Kumar completed her MBBS and Post Graduate Diploma in Clinical Pathology from GMC, Trivandrum, and is a Fogarty Fellow graduate in Bioethics from University of Toronto. She worked as a researcher in the Gastroenterology Dept. of GMC, Trivandrum and in the Liver Clinic of Madras Medical College, Chennai. She retired as Deputy Director General, Senior Grade from ICMR, where she was Program Officer for bioethics, traditional medicine research, and earlier for pharmacology, summer studentship for medical undergraduates as well. She was closely involved in the formulation of several ethical guidelines in India under the aegis of ICMR, Dept. of Ayush & NACO. She is a national & international surveyor for the ethics committee for SIDCER recognition program.

She has pioneered Bioethics Education in India and has been instrumental in initiating the first online PG Diploma course in bioethics in India under ICMR-IGNOU joint initiative sponsored by the NIH, USA. She was a member of international panel of 'President Obama's Commission for the Study of Bioethical Issues', Advisory Council of Drug Information Association, India, and other nationally important committees. She was also Dr. TMA Pai Endowment Chair and Adjunct Professor in Bioethics, KMC, Manipal University. She is now a consultant for bioethical issues and traditional medicine research in India and abroad. She has publications in these areas and is also a reviewer for national and international journals for the same. She is a Faculty for Diploma & Masters course in Bioethics and Clinical research. She is the recipient of ISCR Lifetime Achievement Award 2015 and 'Outstanding International Suveyor of Ethics Committees' 2019. She is a senior consultant for Niti Aayog, BIS, G20, WHO, NIH, EU and other agencies, and is recently appointed as Distinguished Scientist Chair by the Ministry of Ayush (traditional Systems of Indian medicine and Homeopathy).

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Dr. Renuka Munshi Professor & Head, Department of Clinical Pharmacology, Topiwala National Medical College & BYL Nair Charitable Hospital is Chairperson on the IRB of PD Hinduja & KDAH hospitals & IIT-Bombay & Member Secretary, Institutional Ethics Committee. She is Member of number of Expert Committees including: FSSAI Expert Committee (EC) to provide no objection for conducting human intervention studies on novel or non-specified food ingredients/products; FSSAI Expert Committee (EC) for Non-Specified Food and Food Ingredients and DTAB Sub-Committee to evaluate Fixed Dose Combinations (FDCs) considered as irrational

She is Ex-member of the Independent Expert Committee, GOI, Serious Adverse Events (SAEs) reporting of deaths occurring during Clinical Trials and Ex-Member of the Core Training Panel of the Pharmacovigilance program of India.

Dr. Munshi NABH Assessor for Ethics Committees, Coordinator of ADR Monitoring Centre under the Pharmacovigilance & Materiovigilance programs of the Government of India, Principal Investigator of various clinical trials and academic studies and Government funded projects and has authored more than 100 publications in International & National peer reviewed journals.

BRIEF CV

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Dr. Saurendra (Moonoo) Das Have over 33 years experience in clinical practice, teaching and managing all phases of global and domestic clinical research projects of innovative healthcare products and cutting-edge technology medical devices. A start-up specialist having been involved in setting up 8 major healthcare and research organizations across India. Has been trained by Harvard Medical International, USA. Successfully trained more than 12,000 investigators, physicians, dentists, CRC's & CRAs' and other stakeholders including lab and pharmacy personnel, ethics committee members. Been actively involved in clinical research conceptualization, design, set up, trial coordination to close out and publication. Been involved in bids and proposals for all aspects of clinical research projects, designing of SOP for EC, setting up central pharmacy. **Managed and in charge of the 4 sites which became the first clinical trial sites in India to be inspected by US FDA and of another 4 sites which were inspected by EMA.**

Keenly involved in training programs for all stakeholders of clinical research and spreading the awareness of clinical research across the country. Wet lab trainer for ophthalmologists across India, South East Asia and Australia. Trainer in ICH-GCP & clinical research methodologies and publication.