ILSI INDIA

K-FFIG

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

Current Status and Way Forward

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POST CLINICAL STUDIES

for New Foods & Ingredients

-Role of Regulators, FBOs and CROs

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Current Status and Way Forward

Claims on Food/Ingredients

A *nutrition claim* states or suggests that a food has beneficial nutritional properties, such as “low fat”, “no added sugar”, “rich in protein” and “high in fibre”.

A *health claim* is any statement used on labels, in marketing or in advertising that health benefits can result from consuming a given food or from one of its components such as vitamins and minerals, fibre, and ‘probiotic’ bacteria.

For the purpose of regulation 2.2.2 (3);

(i) “Health claims” means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health

Examples of Health Claims

- **Low glycaemic: Lowers blood sugar**
- ***Lowers cholesterol levels***
- ***Weight loss***
- ***Reduces Hypertension***
- ***Increase of bone strength***
- ***Etc..***

Health Claims management across Globe

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USFDA :

- FDA has authorized 12 health claims since 1990
- Authorizes Health Claims That Meet Significant Scientific Agreement (SSA) Standard : Authorized health claim
- Qualified health claims (QHCs) are supported by scientific evidence, but do not meet the more rigorous “significant scientific agreement” standard required for an authorized health claim.

  To ensure that these QHC claims are not misleading, they must be accompanied by a disclaimer

Health Claims management across Globe

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EFSA :

- EFSA is responsible for verifying the scientific substantiation of health claims submitted for authorization in the EU
- Published consolidated list of General function health claims under Article 13
- Claims on disease risk reduction under Article 14
- Updated final list of 4,637 claims was the result of a consolidation process carried out by the Commission, after examining over 44,000 claims supplied by the Member States.
- The complete list was published on the EFSA website in the form of an Access database https://www.efsa.europa.eu/sites/default/files/topic/ndaclaims13.zip

AUSTRALIA

NEW ZEALAND

Etc..

Health Claims in India

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FSSAI :

- Food Safety & Standards Act, 2006
  - Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011
  - Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016
  - Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017
  - Food Safety and Standards (Advertising and Claims) Regulation, 2018
  - Food Safety and Standards (Labelling and Display) Regulations, 2020

Food Trials

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FSSAI :

- There is defined approval process on approval/rejection of a health claim,
- But 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.
- Studies in Indian population would be important to support their safety and efficacy.

Health Claims in India

Clear guidelines for conducting human intervention studies for food products in India is the need of the hour

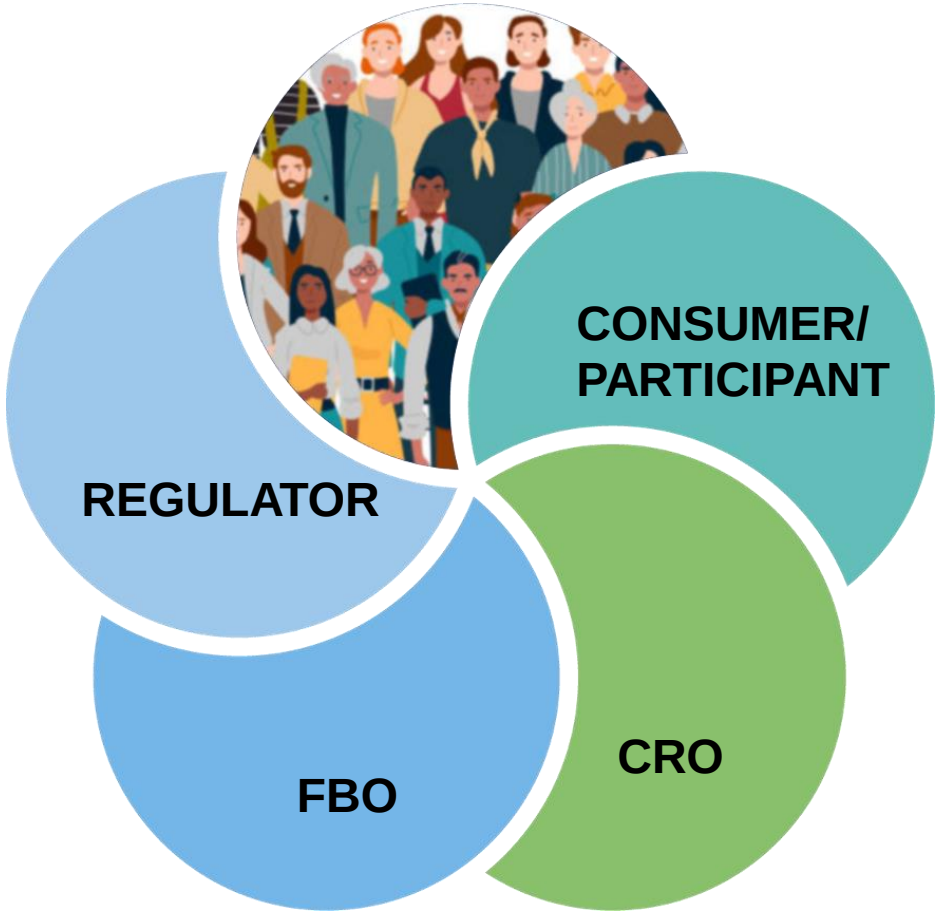
Drug Trials / Food Trials

- Clinical Trials for Drugs under **New Drugs and Clinical Trials Rules, 2019**

Drug Trails	Food 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).	often designed to evaluate specific marketing claims needing scientific substantiation
Drug trials tend to be more explanatory as they document specific drug doses and schedules and specific disease responses.	Food trials tend to be more pragmatic and exploratory as they document human experiences with specific foods in the context of the human diet
drug trials enroll patients with a specific disease type potentially needing the research treatment	Food trials typically enroll healthy individuals
drugs are highly purified and designed to have a specific effect on a disease.	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

Intervention/Evaluation studies and key stakeholders

- PRE-CLINICAL intervention/evaluation studies
- CLINICAL intervention/evaluation studies
- POST-CLINICAL intervention/evaluation studies



Need of Post-Clinical Intervention/Evaluation studies

- Data collected from clinical study is limited…
- Clinical studies are involved with very limited population.
- Trials are conducted in a controlled conditions, conditions could be entirely different when one is taking at home.
- When the product is in the market, consumers are diverse (w.r.t. race, age, etc.) and differ from the data reported in clinical trial.
- Collection of large data and evaluation will allow the FBO to modify (if needed..) to bring better product to public.

Post-Clinical: Role of regulators (FSSAI)

- Providing guidance document on conducting post-clinical studies.
- Providing an app to general public to report on safety and efficacy of the product they use where health claims are made for the product.
- Integration of CRO database to the above database for seamless transfer of data to have complete info for evaluation.

- Establishing statistical models to interpret data.
- Undertaking from FBO and taking commitment from FBO to conduct post-clinical studies before granting the approval.
- To bring clarity to FBOs/CROs on whether Ethics committee approval is sufficient to conduct Food Trial/Post-clinical study or to seek any additional approvals.

Post-Clinical: Role of FBOs

- Commitment to conduct post-clinical studies to gather additional information about a product's safety, efficacy, or optimal use.
- Health/Label claims shall be modified timely based on the information obtained through post-clinical studies.
- FBOs shall constantly make efforts in doing surveys and getting feedback from the population using their products and share info to regulator.

Post-Clinical: Role of CROs

- CRO is a key stake holder in the process.
- Shall be unbiased and shall not yield to the time pressure from FBOs.
- Strict adherence to GCP regulations on ethical conduct of the study.
- Taking all requisite approvals to conduct study.
- Identifying new indications from the data of post-clinical studies.
- Shall contribute to bring guidance documents for all pre-clinical, clinical, post-clinical studies

Post-Clinical: Role of Participants/Consumers

- Commitment to complete the study.
- Unbiased and providing accurate feedback on the product.

Way Forward

- Safety and efficacy against the claims **is critical** to protect consumer's health and wellbeing and generate consumer's confidence.
- Health claims made should be scientifically substantiated.
- A **cause and effect relationship** between a food/constituent/Nutrient/Additive and a claimed effect has to be established.
- Best practices for food clinical intervention studies to be established.
- Various guidance documents to be established for all pre-clinical, clinical, post-clinical studies.
- Modalities of periodic adverse event reporting to regulator shall be worked out.
- Establishing decision tree models on health claims

What to bring in?

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QUALITY

COLLABORATION

Effective Health Claims

Clinical evalution/ intervension studies

INNOVATION

TECHNOLOGY

Thank You