Conducting a Clinical Study (Validating Claims)

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What are Claims?

Truthful, not misleading and are based on data

- Nutrition Content Claim → High/Rich/Source (only with established RDAs)
- Nutrient comparative claim → 2X lower than…
- Non-addition Claim → Does not contain/Free from…
- Nutrient Function Claim → Supports…
- Disease Risk Reduction Claim

Conducting a Clinical Study

Safety, the most important part of compliance of the study product

Planning a Clinical Study

A well defined research question and hypothesis

- Comprehensive review of existing evidence and clearly state how the food intervention will influence the intended health effect

Example:

- Daily intake of iron fortified biscuits for 6 months will significantly reduce the prevalence of anemia among adolescent school girls

Study Design

- Carefully consider:
  - Type (parallel arms/cross over)
  - Method of randomization
  - Blinding (prevents biasness)
  - Selecting intervention and control foods
  - Dietary control and monitoring compliance (metabolic ward; free living)
  - Length of the study (depends on the study design; run-in period; washout period)
  - Type of data analysis
  - Conducting pilot study
  - Number of investigating sites

Outcome Measures

- Primary outcome
  - Answers the principle research question
  - To calculate the sample size
  - Biomarkers: chosen marker must be valid; relationship with clinical outcome the disease

Disease	Biomarker
CVD	LDLc; TC; BP
Osteoporosis	BMD
T2DM	FBG; PPBG; IR

Compliance

- Essential to validate the study results
- Biomarkers may be blood, tissue, urinary, fecal levels of the nutrient or dietary component under study or its metabolite

Component	Biomarker
Protein	Urinary nitrogen levels
Fiber	Stool hemi-cellulose levels
Iron	Serum iron levels
Vitamin D	Plasma 25-OH D levels
Na/Ca/K/Mg	24 urinary levels

Adverse Event Outcome Measures

- Related to intake of food or dietary component
- May range from minor symptoms to serious complications
- Typical questions like “Have you had any adverse events since your last visit?”

Selection of Study Population

- Participant cohort should provide good representation of the population of interest
- Suitable scientific platform to test various food components for the health effect

Sample Size Calculation

- **Power analysis**
  - Determine optimum number of participants
  - Allow conclusions to be drawn with highest degree of confidence
  - Allows for detection of the hypothesized intervention effect
- **Null Hypothesis** → no effect/no relationship between intervention and outcome
- **Alternate hypothesis** → opposite of null hypothesis, implying that a relationship exists between intervention and outcome

Eligibility Criteria

- Variables as:
  - Age
  - Gender
  - Health status
  - Medication
  - Anthropometric and/or biochemical parameters
  - Dietary and lifestyle habits

Test Product & Suitable Control Selection

- Establish intended use of the food product being investigated
- Determine appropriate and effective dose; ensuring bioavailability; appropriate serving size
- Safe handling and storage practices; minimize batch variability
- Determine appropriate control treatment
- Ideally, implement a pilot study to test feasibility, quality control, production and participant acceptability

Clinical Trial Implementation

- Approval from Institutional Research Ethics Board
  - Informed consent; confidentiality; appropriate compensation for participation
- Register the Clinical trial
- Allowance for dropouts
- Compliance assurance and monitoring
- Record keeping and database
- Collection, labeling and storage of samples

- Management of dropouts and missing data – robust statistical analysis
- Reporting adverse events – qualified medical doctor; record AE
- Post experiment communication with participants - Inform the study results

Post Clinical Trial

- Sample analysis
  - Validated operating procedures
  - Triplicates
- Data analysis (without un-blinding the data)
  - Data preparation
  - Descriptive analysis
  - Statistics
- Publishing results - dissemination of results to scientific audience

Thank You