

BUILDING CONSUMER TRUST THROUGH PRODUCT CLAIMS SUBSTANTIATION



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Introduction

Establishing consumer trust is fundamental to the success of any product in the market. Substantiating product claims is essential, not only to assure customers of the product's efficacy and safety, but also to ensure compliance with regulatory requirements, prevent misleading advertising, and foster long-term loyalty among consumers.

By providing clear evidence and transparent communication about product attributes, companies demonstrate their commitment to honesty and integrity. This approach minimises the risk of disputes or regulatory actions and empowers consumers to make informed choices, thereby strengthening brand reputation in the marketplace.

Importance in the Indian Context

In India, consumers are increasingly discerning, and regulatory bodies such as the Advertising Standards Council of India (ASCI) and Food Safety and Standards Authority of India (FSSAI) play a pivotal role in overseeing product claims. Robust substantiation becomes even more critical in this environment. Brands must ensure that all advertised product benefits are supported by scientific data and communicated in a manner that resonates with local consumer expectations while complying with prevailing guidelines. This not only safeguards the brand from potential legal challenges but also establishes credibility and trust with Indian consumers.

Challenging the product claims

Product claims can be

challenged by competitors, regulatory authorities, or consumers. Disputes may arise if the evidence is deemed insufficient, outdated, or not relevant to the specific claims.

Brands must therefore ensure that their substantiation is robust, scientific, and clearly linked to the advertised benefits to withstand scrutiny and protect their reputation in the marketplace. Marketers must back challenged claims with scientific evidence, such as lab results or clinical studies. Keeping this data ready helps brands defend their products quickly and maintain credibility.



Generating Scientific Data

Scientific data can be generated through controlled laboratory experiments, clinical trials, consumer acceptance studies, and rigorous analytical testing.

Engaging independent third-party organisations for assessments or validating results through peer-reviewed studies further strengthens data credibility. These methods ensure that evidence supporting product claims is both reliable and recognised within the scientific community.

Recognised methods for generating scientific data to substantiate product claims include:

- In vitro studies: Testing in controlled laboratory settings, often using cell cultures or biochemical assays to assess specific product properties.
- In vivo human trials: Testing with actual participants to evaluate the product's effects in real-world scenarios, providing robust and directly relevant evidence.

- Expert panel tests: Utilising qualified professionals to assess the product based on established criteria.
- Consumer panel tests: Gathering feedback from target consumers under controlled conditions to gauge perceived efficacy and acceptance.

Employing a combination of these methods enhances the comprehensiveness of substantiation, ensuring the evidence is scientifically sound and reflective of consumer experience.

Guidelines

Depending on the nature of the product claim, the study should be meticulously designed and conducted in accordance with relevant guidelines such as those from the Indian Council of Medical Research (ICMR) or the International Council for Harmonisation - Good Clinical Practice (ICH-GCP). Adhering to these standards ensures the research methodology is scientifically robust, ethically sound, and globally recognised, enhancing the credibility and acceptability of

substantiation data among regulators and consumers.

Regulators have provided detailed guidelines regarding product labelling, and strict adherence to these standards reduces the likelihood of claim rejection. For nutraceuticals intended for health promotion or disease risk reduction, regulatory authorities demand submission of robust scientific studies as part of the approval process.

These studies must demonstrate the validity of claimed benefits, ensuring consumers receive accurate and reliable information. Compliance with these requirements improves the chances of claim approval and reinforces consumer confidence.

If a food product is designed to promote health or reduce disease risk, it approaches regulatory boundaries of a drug-like product. Indian regulators have set clear guidelines on claims that cannot be made on product labels, such as statements implying diagnosis, cure, mitigation, treatment, or prevention of specific diseases unless expressly permitted. Claims suggesting medicinal properties or those that could mislead consumers about intended use are strictly prohibited.



Only approved and substantiated claims, supported by robust scientific evidence, may be used on food product labels, as outlined by FSSAI and other regulatory bodies. Brands must ensure full compliance with these standards, avoiding unsubstantiated or prohibited claims to prevent regulatory action and uphold consumer trust.

Randomised Controlled Trials: The Gold Standard Randomised Controlled Trials (RCTs) are regarded as the gold standard for demonstrating product efficacy. By randomly assigning participants to intervention or control groups, RCTs eliminate bias and provide robust, statistically significant data about actual benefits for the target consumer population. This approach validates claims with high scientific rigour and enhances product credibility and acceptance among regulators and consumers.

The first step is to define the product label claim for which data is required. Based on the claim, study objectives and outcome

measures are defined, helping to establish a robust scientific protocol, considering the study population, age group, and relevant conditions. Clear articulation of

the claim ensures focused and relevant research, guides methodology and endpoints, and facilitates transparent communication with regulatory authorities and stakeholders, reducing ambiguity and strengthening substantiation.

Study Investigator, Protocol Development, and Ethics Compliance

A qualified Investigator, preferably a medical doctor with specialisation in the relevant field of research, should assume overall responsibility for leading the study. To ensure the scientific rigour and comprehensiveness of the study protocol, it is advisable to involve a nutritionist in the planning and designing process. This collaborative approach enhances the robustness and relevance of the research methodology.

Once the study protocol is drafted and consensus among all stakeholders is achieved, the next critical step is to obtain approval from an Institutional / Independent Ethics Committee (IEC). This approval must be sought in accordance with the

prevailing ethical and regulatory guidelines. It is essential that the Ethics Committee be registered with the Central Regulatory authorities, as this ensures both regulatory compliance and the upholding of high ethical standards throughout the study.

Following receipt of Ethics Committee approval, the study should be registered on the Clinical Trials Registry-India (CTRI) website. Registration on this platform further contributes to the credibility and transparency of the study, reinforcing its acceptance among regulatory authorities and the scientific community.

Evaluation Components within Study Protocols

A comprehensive protocol for product claim substantiation typically incorporates three distinct evaluation components. These elements are essential to ensure a rigorous and multi-faceted assessment of product efficacy, thereby enhancing the reliability of study outcomes.





1. Clinical Examination

The clinical examination is conducted by the Investigator, who uses established clinical scales tailored to the specific benefits claimed for the product. Examples of assessment tools include measurement of vital parameters, anthropometric indices, psychometric scales, Satiety Index, and Quality of Life (QOL) questionnaires and many more such validated scales. These instruments are chosen to offer objective, clinically relevant insights into the claimed effects.

2. Objective Assessments

Objective assessments involve the use of specialised instruments or laboratory tests to generate quantifiable physiological data. Typical examples include non-invasive devices for body composition or skin analysis, as well as measurement of physiological markers in blood samples. These objective measures are critical for demonstrating the efficacy of the product in a scientifically robust manner.

3. Participant Feedback

In addition to clinical and objective evaluations, participant feedback is captured through structured questionnaires. This approach is designed to collect subjective experiences and perceptions

directly from study participants, offering valuable insights into the real-world impact of the product from the consumer's perspective.

Integrating these components ensures a holistic, scientifically robust evaluation and reliable study outcomes.

Statistical Analysis and Interpretation of Study Data

A rigorous statistical analysis is a critical component in substantiating study outcomes or product claims. It is imperative that the study is adequately powered from a statistical standpoint; insufficient statistical power may result in the data being rejected by regulatory authorities. To ensure validity and reliability, careful statistical planning must be undertaken at the outset, which includes precise calculation of the required sample size and the selection of appropriate statistical tests tailored to the study design and endpoints.

The presentation of results should include confidence intervals and p-values, which are essential for demonstrating the statistical significance and reproducibility of the findings. Employing this comprehensive and methodical statistical

approach not only enhances the credibility of the study but also increases its acceptance by regulatory bodies.

Common Reasons for Claim Rejection

Claims may be rejected by regulatory authorities if critical aspects of the research process are overlooked. An incorrect trial design or mismatch between trial design and claim wording can render endpoints insufficient for regulatory approval. If outcomes measured do not closely align with the claim statement, the evidence may be considered inadequate.

Using a non-standardised or variable product formulation during the trial undermines result validity. Regulators require that the tested product matches the marketed product exactly; any variation can raise doubts about reproducibility and reliability. Another common reason for rejection is an underpowered study design, where too few participants yield unreliable or inconclusive results, regardless of observed trends.



To avoid rejection, trial design, endpoints, and product formulation must be tailored to the claim, and the study must be sufficiently powered to detect meaningful effects.

Rigorous planning and alignment with regulatory expectations are vital for successful claim substantiation and approval.

Collaboration between Industrial bodies and Regulators

Going forward, regulators and industry should adopt a collaborative and proactive approach to align trial designs with regulatory expectations. Early and continuous engagement can pre-empt pitfalls, ensuring studies generate data that meets scientific and regulatory standards. This alignment streamlines

approval processes and helps avoid wasted resources and post-study rejections.

One key recommendation is for regulatory authorities to offer a pre-vetting mechanism for claim substantiation protocols. Early feedback on study design, endpoints, and methodology enables industry stakeholders to refine protocols before trials commence. Pre-vetting fosters transparency, reduces ambiguity, and enhances the quality and acceptance of scientific evidence for product claims. This collaborative model builds trust, accelerates innovation, and ensures consumer protection in the marketplace.

Key Takeaways

For Industry: Invest in robust, scientifically designed studies that adhere to regulatory standards and best practices. Ensure scientific findings are translated into clear, consumer-friendly, and responsible communication to enhance

product credibility and consumer trust.

For Regulators: Provide clear, accessible pre-submission guidance to streamline the approval process. Foster collaboration with industry stakeholders to minimise post-study claim rejections and support the development of reliable, evidence-based products.

For Consumers: Critically read product labels and proactively demand products with evidence-backed claims. Making informed choices helps protect consumer interests and encourages higher standards across the industry.

Ultimately, claim substantiation is not only a compliance exercise but also a trust-building mechanism for the Indian food industry. By aligning science, regulation, and communication, stakeholders can create a transparent ecosystem that benefits consumers and brands alike.

