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Clinical Trials of Clinical Trials

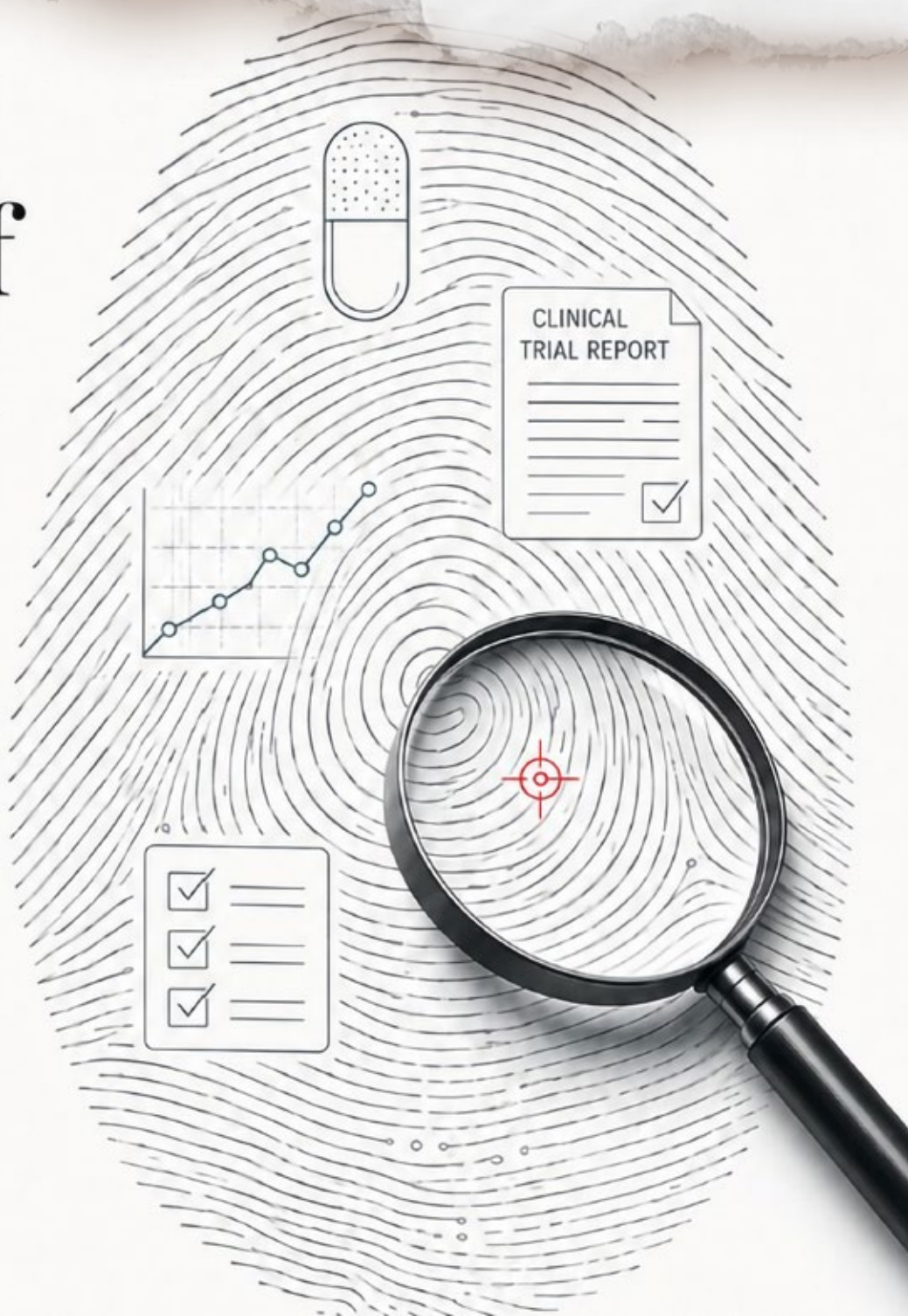
Who will audit the evidence behind clinically tested supplements?

INSPIRED BY

DR. EDMOND LOCARD

“Every contact leaves a trace.”

— LOCARD'S EXCHANGE PRINCIPLE
APPLIED TO NUTRACEUTICAL SCIENCE





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FROM THE EDITOR: GROWTH MUST NOW EARN TRUST

Dear Reader,

The nutraceutical industry is entering an unusually important phase.

Demand is expanding. Science is advancing. Digital commerce is accelerating. New therapeutic categories are reshaping consumer behaviour. Yet beneath this momentum lies a more difficult question:

Are we building a larger industry; or a more credible one?

This edition of The Nutra Economist is not centred on one ingredient, one health condition or one commercial trend. It is centred on the discipline required to convert opportunity into responsible growth.

Our first investigation asks an uncomfortable but necessary question: **Who audits the evidence behind the phrase “clinically tested”?**

A published study can add authority to a product. But publication alone does not prove that the correct formulation was tested, that the registered protocol was followed, that the primary endpoint succeeded or that the eventual advertising claim faithfully represents the result.

The distance between a clinical study and a marketing slogan can be surprisingly long.

Every link in that journey matters: the trial batch, protocol, source data, publication, marketed formulation and final consumer communication.

The industry must therefore move beyond counting papers and begin examining the quality and continuity of the entire evidence chain. Better science should earn a commercial advantage. A weak observational study and a properly registered finished-product randomised trial cannot continue to travel under the same “clinically proven” badge.

As nutraceuticals become more clinically ambitious, evidence governance can no longer remain a matter of presentation. It must become industry infrastructure.

The second theme in this edition is the rapid emergence of the GLP-1 economy.

Medicines such as semaglutide and tirzepatide have changed the public conversation around obesity, appetite and metabolic health. Their influence is already extending beyond the prescription itself—into protein nutrition, fibre, digestive support, muscle preservation and post-treatment nutritional care.

But this opportunity carries an important warning. The popularity of GLP-1 therapy is not permission to place drug-like expectations on supplements. Phrases such as “natural Ozempic” may attract digital attention, but they do not build a responsible or durable category.

The more valuable opportunity lies in understanding the nutritional journey surrounding medically supervised weight management: reduced food intake, gastrointestinal discomfort, protein inadequacy, lean-mass loss and the challenge of sustaining healthier behaviour over time.



PRIYANKA SRIVASTAVA

Chairperson, Nutrifitoday

The injection may have created the conversation. Responsible nutrition must now determine what the industry contributes to it.

Our third article widens this discussion into an investment thesis.

India's next major supplement opportunity may not be another multivitamin, whey powder, gummy or fashionable botanical. It may be a broader health platform built around metabolic strength; helping consumers manage weight and metabolic risk without surrendering muscle, energy or future independence.

This represents a larger shift from **product consumption to problem ownership**.

Consumers will increasingly expect more than another jar. They will expect a defined use case, appropriate pricing, credible guidance, measurable progress and a reason to continue. The strongest businesses will not merely formulate products. They will design systems around specific life stages, nutritional gaps and health transitions.

Read together, the articles in this edition make one connected argument.

The next phase of nutraceutical growth will be shaped by three forms of discipline: scientific discipline, commercial discipline and communication discipline. Scientific discipline means testing the product that is actually sold and matching every claim to the strength of its evidence.

Commercial discipline means identifying consumers who genuinely need the product, can reasonably afford it and have a credible reason to repurchase it.

Communication discipline means resisting the temptation to convert every emerging medical trend into an exaggerated supplement promise.

For India, this is a significant strategic moment. We possess the manufacturing capability, ingredient heritage, clinical talent, digital reach and entrepreneurial ambition required to build globally relevant nutrition businesses. What we now require is a stronger culture of evidence, transparency and category stewardship. Growth without trust is temporary.

Innovation without validation is vulnerable. A claim without traceability is merely advertising. The opportunity before the industry is therefore larger than selling more supplements. It is to build an ecosystem in which responsible nutrition becomes commercially rewarding—where credible research is visible, honest communication is differentiated and products are designed around meaningful outcomes rather than fashionable ingredients.

I invite you to read this edition not as three separate articles, but as three perspectives on the same future:

**EVIDENCE MUST
BE EXAMINED.
EMERGING
OPPORTUNITIES
MUST BE
APPROACHED
RESPONSIBLY.
INVESTMENT
MUST PROGRESS
FROM PRODUCT
PROLIFERATION
TOWARDS
CREDIBLE
HEALTH
PLATFORMS.**

The nutraceutical industry is scaling. The defining question is whether its standards will scale with it.





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CLINICAL TRIALS OF CLINICAL TRIALS

Who Will Audit the Evidence Behind “Clinically Tested” Supplements?

A forensic examination of the journey from formulation to consumer claim.

In 1910, French criminologist Dr. Edmond Locard established the first modern police crime laboratory. His enduring principle was simple:

Every contact leaves a trace.

Nutraceutical clinical research needs the same forensic discipline.

Every study leaves traces—in its product batch, protocol, registry, data, publication and marketing claim. Yet no institution reconstructs the chain.

A PubMed-indexed, randomised, double-blind, placebo-controlled study does not prove that its primary end-point succeeded, its effect was meaningful, all outcomes were disclosed, the marketed formula matches the tested product, or the advertising reflects the result.

The industry must therefore ask:

Who will conduct the clinical trial of the clinical trial?

The answer is an independent evidence-forensics system auditing the journey from formulation to claim.

The badge PubMed never issued

PubMed is a search resource, not a product-certification authority. Publication means that a manuscript entered the scientific record; it does not mean that a product was independently validated.

Commercial language escalates:

An ingredient was studied → a formula was tested → a paper was published → it appeared in PubMed → the product became “clinically tested” → the brand became “clinically proven.”

Published describes an address.

Clinically tested describes a process.

Clinically demonstrated describes a result.

Independently replicated describes confidence.

When an uncontrolled observation and a prospectively registered finished-product RCT carry the same badge, weak evidence competes with strong evidence. Better science earns little market advantage.



AMIT SRIVASTAVA

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Member-Nutra Task Force
Office of PSA To Government of India

Evidence laundering

“Evidence laundering” occurs when a limited finding gains authority through publication, public relations and marketing. One extract may be used to promote another. A secondary endpoint may conceal a failed primary endpoint.

A post hoc subgroup may be presented as pre-planned. One positive time point may become the headline. A short study may become “proven safe,” and an uncontrolled observation may become proof of causation.

A genuine paper can still support a misleading implication. A 2024 investigation of functional-food trials by five Japanese CROs examined 76 registered trials, 32 publications and 11 promotional communications. Around 72% of publications were rated at high risk of selective outcome reporting, while spin appeared in conclusions and advertising. Comparing registry, paper and promotion revealed the distortion.

In the US green-coffee case, the FTC alleged that measurements were altered, trial duration changed and treatment allocation mistated before the study supported weight-loss claims. The lesson is not that industry-funded research is inherently unreliable. A polished manuscript simply cannot replace source-data integrity.

POM Wonderful established another principle: evidence requirements should rise with the seriousness and consequences of the claim. General-wellness language should not require a pharmaceutical programme. Disease-treatment, prevention or high-risk claims should approach pharmaceutical standards. The answer is claim-proportionate evidence governance.

The missing owner of the evidence chain

Ethics committees protect participants. Registries record intentions. CROs execute studies. Investigators generate data. Journals review manuscripts. PubMed indexes them. Regulators assess compliance.

None routinely asks:

- Was the correct product tested?
- Was the registered protocol followed?
- Do the source data support the analysis?
- Does the paper report the complete result?
- Does the commercial claim represent it honestly?

That unoccupied space is the case for a “trial of the trial.”

Five audits every claim-generating study needs

Product identity: Is the intervention characterised and traceable to the marketed product—including specification, strain, dose, ratio, delivery system, process and trial batch?

Protocol: Did the study follow its registered protocol and statistical plan? Changed endpoints, populations, time points and subgroup analyses must be labelled exploratory.

Data: Do source records, laboratory reports, datasets and code support the numbers? Risk-based audits should detect altered values, unexplained exclusions, duplication, randomisation problems and missing adverse events.

Publication: Were all prespecified outcomes, exclusions, protocol changes and adverse events reported? A paper can mislead through omission.

Claim: Does advertising match the formulation, dose, population, duration, endpoint, effect size, uncertainty and total evidence?



DR. EDMOND LOCARD

Pharma-grade integrity, nutraceutical-proportionate execution

The industry often presents a false choice between full pharmaceutical development and a low-cost observation. A credible middle path exists.

Ethics approval, prospective registration, locked protocol and statistical plan, defined primary endpoint, justified sample size, appropriate control, randomisation, between-group analysis, adverse-event reporting, batch traceability and public results should be non-negotiable.

Low-risk studies may use central monitoring, decentralised procedures, pragmatic designs and risk-based verification. Monitoring and replication can vary with risk and claim seriousness.

Pharma-grade integrity. Nutraceutical-proportionate execution.

Finished formulations must become central

Ingredient research establishes plausibility, mechanism and dose rationale. It does not prove that a finished product works.

Commercial formulas may differ in dose, ratio, extract, strain, delivery, stability and interaction. Positive studies on separate ingredients do not prove their combination.

Finished-formulation trials should become the default basis for product claims. Analytical bridging may suffice when actives, doses, ratios, specifications, process and dosage form remain equivalent. Material changes in ingredients, dose, strain, extract, release profile, population or claim should require new efficacy evidence.

Post-market evidence: valuable but incomplete

Post-marketing studies can reveal adherence, tolerability, safety signals and real-world effectiveness. But uncontrolled studies cannot separate product effect from placebo response, natural fluctuation, lifestyle change, concurrent treatment, self-selection or dropout.

Confirm efficacy first. Learn continuously thereafter.

Credible programmes should be registered, identify the product, define outcomes in advance, collect baseline and follow-up data, monitor adverse events and disclose all findings. A customer-satisfaction survey should never become clinical proof.

The Clinical Evidence Passport

Every product using clinical language should carry a QR-linked public evidence passport showing the formulation and trial batch; registry number and protocol; primary endpoint; sample size; effect size and clinical relevance; adverse events and null findings; equivalence status; limitations; and exact claim supported.

It should answer:

What was demonstrated, in whom, using which formulation, for how long and with what certainty?

Governance without another paid seal

The sector needs an independent Nutraceutical Evidence Assurance Council—not another certification business.

It should verify product identity, assess whether a trial supports its claim, audit data proportionately, compare protocol with publication, review advertising concordance and maintain the evidence passport.

Sponsors should contribute to a pooled fund rather than select reviewers. Auditors must be independent of trial design, execution and publication. Fees should purchase assessment, not approval. Negative decisions, null results, corrections and withdrawals must remain visible.

FSSAI should retain authority over claims and enforcement. CTRI should remain the registry. An independent council should provide assurance. Disease-treatment or prevention claims should enter the medicinal pathway.

India can combine EU-style claim discipline, Australian-style intermediate assessment, WHO transparency, ICH proportionality and FTC-style product-to-claim scrutiny.

The way forward

India can begin without waiting for a new law:

1. Develop a Responsible Nutraceutical Clinical Evidence Standard.
2. Review marketed products carrying clinical claims.
3. Pilot finished-formulation trials under independent assurance.
4. Launch public evidence passports.
5. Seek regulatory recognition.

The sector does not primarily need more papers. It needs fewer broken links between the formulation studied, the outcome measured, the publication produced and the promise made to consumers.

Dr. Locard taught that every contact leaves a trace. The credibility of nutraceutical science depends on whether those traces are preserved, connected and honestly interpreted. The industry has spent decades conducting clinical trials of supplements. It is now time to conduct clinical trials of the clinical trials.





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INDIA'S GLP-1 GOLD RUSH: THE REAL OPPORTUNITY MAY BE BEYOND THE INJECTION

THE GLP-1 ECONOMY

The opportunity beyond the injection



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Estimated India GLP-1 support supplement
market by 2030

GLP-1 was once a term heard mainly inside endocrinology clinics. Today, it has become one of the most commercially powerful expressions in healthcare, weight management and consumer wellness.

The rise of semaglutide and tirzepatide transformed public understanding of obesity treatment and metabolic health. In India, the prescription GLP-1 market reached approximately ₹1,906 crore in moving annual sales by May 2026, according to Pharmarack data cited in the market intelligence report. From just ₹127 crore in 2022, this represents extraordinary category expansion.

But the more interesting business opportunity may not be limited to injectable medicines. A parallel market is emerging around nutritional products intended to support appetite balance, blood-sugar management, digestive health and post-GLP-1 nutritional needs.

The injection created the market. Supplements are now trying to widen it.

A Market Built Around an Affordability Gap

Even after generic entry, prescription GLP-1 therapy remains inaccessible to a large section of Indian consumers. Supplements priced between approximately ₹350 and ₹1,300 per month occupy a substantially lower affordability tier.

This does not make berberine, fibre or botanical formulations substitutes for prescription medicines. Their clinical effects are generally more modest and their regulatory classification is entirely different. However, many consumers do not begin their journey by studying clinical effect sizes. They begin with a Google search, an Instagram video or the phrase “nature’s Ozempic.”

That search behaviour has created a new commercial funnel. The report estimates that India’s GLP-1-support supplement segment could already be worth ₹220-300 crore in 2026 and may reach ₹700-950 crore by 2030. These are triangulated planning estimates rather than independently audited market figures, but the direction is commercially significant. India is projected to be among the fastest-growing markets for GLP-1 nutritional support, potentially expanding at a 16.8% CAGR through 2035.

India’s diabetes burden, rising obesity, growing ingredient literacy and digital supplement adoption provide the underlying demand. But successful companies will need to understand that this is not one homogeneous consumer category.

Four Consumers, Four Different Needs

The first segment is the young, weight-conscious consumer attracted by viral content. This buyer wants convenience, visible results and a low-friction trial format. Gummies, effervescent and compact capsules can perform well here, but repeat purchase may collapse if expectations have been inflated.

The second segment comprises consumers with prediabetes or diabetes who are looking for nutritional support alongside lifestyle management. They are more likely to consult doctors, dietitians, online pharmacies and evidence-oriented platforms. Credibility matters more than celebrity promotion.

The third—and potentially most valuable—segment consists of people currently using or discontinuing prescription GLP-1 therapy. Their concerns may include muscle preservation, digestive discomfort, adequate protein and fibre intake, and maintaining healthier routines after medication.

This “bridge” cohort has higher intent, but it must be approached responsibly. Supplements should not be presented as a mechanism for replacing prescribed treatment or independently managing withdrawal.

The fourth segment includes gut-health and fibre seekers. Ingredients such as psyllium and inulin fit naturally into this space because satiety, gastrointestinal comfort and metabolic health are increasingly viewed as connected rather than separate categories.

The Winning Product May Be a System, Not a Pill

Capsules currently account for an estimated 48% of the Indian GLP-1-support supplement category. However, gummies and medical-nutrition formats are growing faster. Consumers are also frequently “stacking” products—buying a berberine capsule from one company and a fibre supplement from another. This behaviour suggests that the next competitive advantage may come from developing structured nutritional systems rather than simply selling higher-dose berberine.

A credible portfolio could include a metabolic-support capsule, a prebiotic fibre product, a convenient entry format and a clinically framed nutrition programme. The opportunity is not to create a nutraceutical imitation of Ozempic. It is to address the nutritional gaps surrounding the GLP-1 consumer journey.

Distribution must follow consumer intent. E-commerce marketplaces presently account for an estimated 46% of sales, followed by D2C-integrated retail at 24%. Quick commerce, while smaller, is growing rapidly. Pharmacy and clinical channels remain relatively underdeveloped, creating space for companies capable of earning physician and dietitian confidence.

Trust Will Decide the Winners

The biggest commercial risk is also the industry’s biggest strategic opening: credibility.

Independent testing has reportedly identified potency gaps in some berberine products. Meanwhile, phrases such as “natural Ozempic” can create expectations that botanical supplements cannot responsibly fulfil. Gastrointestinal side effects, drug interactions and inconsistent warnings further weaken consumer confidence.

The strongest brands will therefore compete on proof rather than exaggerated promise. Batch-specific certificates of analysis, NABL-accredited testing, transparent ingredient quantities, interaction warnings and realistic communication can become commercial differentiators.

Regulatory discipline will be equally important. Indian nutraceutical regulations do not permit supplements to claim that they treat diabetes or obesity, replicate GLP-1 medicines or directly replace prescribed therapy. Even using “GLP-1” prominently in product branding may attract closer scrutiny if the overall communication implies drug-equivalent action.

The market opportunity is real, but it is not a licence for opportunistic labeling.

India’s GLP-1-support economy will eventually divide into two camps: products that merely borrow the popularity of the injection, and businesses that understand the wider nutritional journey created by it.

The first group may generate rapid clicks. The second has a chance to build a durable category.

INDIA'S NEXT SUPPLEMENT GOLD RUSH WILL BE BUILT ON METABOLIC STRENGTH

For years, India's supplement market has grown by adding more products to familiar shelves: multivitamins, calcium, whey protein, immunity blends, gummies and beauty supplements. These categories will continue to sell, but they are becoming increasingly difficult places in which to build an investment-grade business. Formulations are readily replicated, consumers compare prices instantly, and digital marketplaces often reward discounting more than scientific differentiation.

The next large opportunity will emerge not from another ingredient story, but from solving a more consequential problem: how Indians can lose weight, manage metabolic risk and age without losing muscle, nutrition or functional strength.

The underlying need is already visible. The ICMR-INDIAB study estimated that 11.4% of Indians have diabetes, 15.3% have prediabetes, 28.6% have generalised obesity and 39.5% have abdominal obesity. Dyslipidaemia was estimated at 81.2%. Abdominal obesity is particularly important because it identifies a much larger population than diagnosed diabetes: people who may still feel healthy but are moving towards insulin resistance, hypertension and future loss of independence. This is not simply a disease market. It is a vast "metabolically vulnerable" consumer market.

The investible cohort, however, is not all of India. It is primarily the country's urban and affluent Tier-2 adults between roughly 35 and 59 years of age—people with regular incomes, growing health anxiety and sufficient purchasing power to sustain a monthly regimen. India's middle class is projected to reach about 715 million people by 2030–31, while Tier-2 and smaller cities contributed around half of incremental online retail orders in 2025. The opportunity is therefore geographically broader than the metros, but it remains income-sensitive.

Affordability must be treated with unusual discipline. India's average urban monthly per-capita consumption expenditure was ₹6,996 in 2023–24, while the top 5% of urban consumers averaged ₹20,310. A supplement programme costing ₹1,500 a month would absorb more than one-fifth of average urban per-capita expenditure but only about 7% of expenditure among the top urban segment.

That makes ₹899–₹1,499 the more realistic range for a core monthly product, with higher prices justified only when diagnostics, dietitian support or measurable monitoring are included. The most powerful market catalyst is the democratisation of GLP-1 therapy. Semaglutide patent protection expired in India in March 2026, opening the market to lower-cost versions from Indian manufacturers. This will expand medically supervised weight management beyond a narrow elite.

But the supplement opportunity is not to imitate pharmaceutical weight loss or make irresponsible "natural Ozempic" claims. It is to address the nutritional problems that may accompany rapid weight reduction: low protein intake, micronutrient inadequacy, gastrointestinal discomfort, loss of lean mass and poor long-term maintenance. Leading obesity and nutrition organisations now explicitly recommend adequate protein, strength training, nutrient-dense diets and management of gastrointestinal effects alongside GLP-1 therapy.

The Next Big Bet in Indian Supplements



The winning proposition should therefore be "metabolic longevity," not merely slimming. Its promise is simple: lose fat without surrendering muscle, energy or future resilience. The hero product could be a compact, protein-forward, low-sugar nutritional format designed for reduced appetite and Indian dietary patterns. Around it should sit an eight- to twelve-week protocol that tracks waist circumference, protein adequacy, functional strength, digestive tolerance and, where clinically appropriate, metabolic markers. This converts a commodity product into an outcome-oriented system.

The commercial model matters as much as the formulation. EY's Indian OTC research found that more than 80% of consumers rely on healthcare professionals or experts for first-time purchases, while experience and brand trust become increasingly important for repeat buying. This suggests a clear route to market: clinicians and qualified nutrition professionals create initial trust; digital platforms, e-pharmacies and subscriptions manage replenishment. A pure influencer-led D2C strategy may generate attention, but it is poorly matched to a condition-led category in which credibility and adherence determine lifetime value.

The best adjacency is women's midlife health. Menopause should not be treated as an isolated hot-flush or calcium category. It intersects with changes in body composition, cardiovascular risk, sleep and bone density. A company that first establishes authority in metabolic strength can extend naturally into a clinically structured women-40-plus platform and later into healthy ageing, mobility and muscle preservation. This is also where the investment moat will be built.

The winners will combine India-specific evidence, transparent dosing, claim governance, professional referral networks, high repeat rates and low dependence on marketplace discounting. FSSAI already places health supplements and nutraceuticals within a defined regulatory framework; scientific substantiation and disciplined claims should therefore be treated as commercial assets, not compliance afterthoughts.

India's next supplement champion will not be the company with the largest catalogue. It will be the company that identifies a high-need consumer, earns clinical trust, measures progress and remains relevant across weight management, midlife and ageing. The real opportunity is not another bottle. It is a metabolic-care platform built around strength, adherence and responsible nutrition.



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THE BRAIN HEALTH BOOM: WHERE SCIENCE MEETS HYPE

Brain health has become one of the busiest intersections in nutraceutical industry. It forms part of a broader “health span” wave, increasingly folded into gut-brain and stress-resilience formulations, which, now is being supported by a growing body of RCTs and network meta-analyses.

But headline market figures often fail to capture the more nuanced, domain-specific realities revealed by the clinical literature. A closer look at the evidence shows where the science truly stands.

The Market Backdrop:

Brain health supplements were valued at roughly \$12.6 billion in 2025, projected to reach nearly \$14 billion in 2026 and approach \$36 billion by 2035 (CAGR ~11%). The nootropic sub-segment alone was valued at \$2.3 billion in 2024, trending toward \$5 billion by 2034.

Yet product launches in this space are growing modestly with about 4% annually, suggesting the growth is being driven by reformulation and category convergence (cognition folded into healthy aging, sports nutrition, and stress/mood products) rather than a wave of novel single-ingredient entrants along with several compound formulations.



DR. SHALINI SRIVASTAVA
Executive Director
Bioaxion

Cherry On the Pudding: The Clinical Evidence

A methodologically rigorous recent network meta-analysis in healthy older adults (Feng X et al, 2006), evaluated plant-derived actives across cognitive domains in healthy older adults (PROSPERO-registered, PRISMA-NMA compliant).

It pooled 25 RCTs with 1,861 participants evaluating efficacy of 9 plant active substances (Bacopa monnieri, Guarana, Ginkgo biloba, Caffeine, Wild Green Oat, Curcumin, Blueberry, Tart Cherry and Raisin), searched across four databases.

The paper provides a valuable reference point, highlighting why claims based on a single study or ingredient are often overstated: the effects may be genuine, but they are typically domain-specific, modest in magnitude, and supported by varying levels of evidence.

Domain-wise Analysis - Data Speaks:

Learning and memory:

Based on 23 studies, Raisin (MD 1.09, 95% CI: 0.46-1.71), tart cherry (MD 0.96, CI 0.13-1.78), and Bacopa monnieri (MD 0.49, CI: 0.07-0.90) showed statistically significant advantages over placebo.

As per Surface Under the Cumulative Ranking Area (SU-CRA), a scale rating treatment efficacy probability during meta-analysis, raisin (95.1%) and tart cherry (89.5%) topped the rankings, though the head-to-head comparison between the two was not statistically significant (MD 0.13, CI: 0.90 to 1.16), a good reminder that SUCRA rankings describe probability of being “best,” not the size or certainty of a difference.

Executive function:

When data from 16 studies were analysed, this domain had the clearest signal. A Bacopa monnieri + lycopene + astaxanthin + vitamin B12 compound (MD 1.28, CI 0.78-1.78), curcumin (MD 1.12, CI 0.72-1.70), tart cherry (MD 1.21, CI 0.47-1.96), and Ginkgo biloba (MD 0.30, CI 0.01-0.59) all beat placebo significantly.

Notably, the compound formulation consistently outperformed single ingredients such as Bacopa monnieri. This can be attributed to multi-target synergistic effect of the formulation such as antioxidant and anti-inflammatory effect of bacosides, BDNF-upregulation by lycopene, astaxanthin's effect on phospholipid hydroperoxides and neuroprotection by methylcobalamin.

Complex attention:

This domain served as a weak spot. No plant active substance showed a statistically significant advantage over placebo; confidence intervals overlapped extensively across all interventions. This is worth flagging explicitly, since “improves focus/attention” is one of the most common marketing claims in the cognitive-supplement category.

Language Function & Verbal Fluency:

With only four studies, the evidence for this domain is limited and should therefore be interpreted cautiously. Bacopa (MD 0.75, CI 0.29-1.21) and raisin (MD 0.55, CI 0.10-1.00) demonstrated significant benefits; however, the small evidence base limits the confidence with which these findings can be generalized.

Perceptual & Motor Function:

Findings from the limited number of studies suggest a potential benefit of guarana (MD 1.09 vs. caffeine, CI 0.35-1.85) for perceptual-motor performance, possibly related to its caffeine, polyphenol, and xanthine content. However, because the analysis was based on only three trials and the network was sparsely connected, the evidence was characterized as extremely weak and exploratory.

Where The Industry Is Heading

Based on the above evidence, polyphenol-rich whole foods like raisin and tart cherry, outperformed purified extracts of similar compound classes such as blueberry in the memory domain. The outcome is consistent with the fact that the whole-food matrices consisting of fiber and organic acids, along with the bioactives, may act synergistically rather than the isolated compound alone. Three major structural shifts show up consistently across supplier and market-intelligence sources for 2026:

- A. Single-pathway “brain booster” framing is giving way to systems claims such as gut-brain axis, metabolic health, stress, and sleep bundled together rather than isolated cognition claims.
- B. Cognition is migrating into adjacent categories. Sports and active-nutrition launches carrying cognitive/mental claims have grown 108% over five years. Cognition is no longer a standalone category, but a claim layer added onto existing formulations.
- C. Healthy aging has absorbed cognition as a sub-claim within a broader health span narrative with categories such as aging and vitality.

The data also speaks about translational gaps. The industry's next big leap won't come from another flashy ingredient, rather it will come from longer, better-powered trials that can truly validate claims.

THE R&D GRAIL SHOW

EPISODE 7

WHAT'S YOUR PATHWAY? The Pharmacology of Nutra

Nutrify Today Academy's seventh R&D Grail session brought together scientific, clinical, academic, and industry perspectives to examine one of the most important frontiers in nutraceutical science: the pharmacology of nutraceutical ingredients. Framed by Nutrify Today Academy Team, Dr. Muneeb opened the event on behalf of Nutrify Today Academy, the discussion moved beyond broad wellness narratives and into a more rigorous question: how should nutraceuticals be studied, positioned, and substantiated when their biological activity is real, but their mechanisms are often complex, multi-targeted, and formulation-dependent ?.

Event context

The session was introduced by Dr. Muneeb, a toxicologist associated with new product development at Nutrify Today and serving as Head of Nutrify Today Academy, who outlined the agenda around the pharmacology of nutraceutical ingredients, their distinction from pharmaceuticals, the challenges of safety and efficacy assessment, the role of microbiome modulation, advances in delivery systems and AI, and the regulatory considerations shaping the category. The event featured Dr. Prasad Thakurdesai, (Chief Scientific Officer and Vice President, Indus Biotech Limited,) Dr. Shalini Srivastava, (Executive Director-Bio-Axion Innovations, Mumbai) and Prof. Sayeed Ahmad, (Director Centre of Excellence in Unani Medicine, SPER, Jamia Hamdard) with Dr. Balkumar Marthi (President, Nutrify Today Academy) later joining and steering parts of the discussion as moderator.

Why this topic matters

The panel made clear that nutraceutical pharmacology can no longer be discussed in generic terms alone. As ingredient systems become more sophisticated through concentrated extracts, phytosomes, liposomes, and other advanced delivery formats, the old assumption that a nutraceutical merely "supports health" without requiring mechanistic clarity is no longer sufficient for credible R&D, regulatory positioning, or market trust.

MODERATOR



Dr. Balkumar Marthi

President, NutrifyToday Academy
(ex-Unilever R&D; former Dean of Innovation, GITAM University)

PANELISTS



Dr. Prasad Thakurdesai

Chief Scientific Officer and Vice President,
Indus Biotech Limited, Pune, India.



Dr. Shalini Srivastava

Executive Director-BioAxion Innovations,
Mumbai, Maharashtra, India.



Prof. (Dr.) Sayeed Ahmad

Director Centre of Excellence in Unani Medicine,
School of Pharmaceutical Education and
Research, Jamia Hamdard (Hamdard University),
New Delhi, India.

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This transition is especially relevant for nutraceutical R&D teams because modern products are increasingly expected to demonstrate not just benefit, but product-specific rationale, defensible endpoints, and safety at intended conditions of use. The conversation repeatedly emphasized that the future of the category depends on moving from generic claims to evidence-backed structure-function and mechanism-linked positioning.

Defining the pharmacology of nutra

Dr. Muneeb set the foundation by revisiting pharmacology as the study of how substances interact with living systems through pharmacodynamics and pharmacokinetics, including absorption, distribution, metabolism, and elimination. In the nutraceutical context, that foundation matters because these ingredients are expected to provide health benefit while remaining distinct from drug claims and drug positioning.

The panel described nutraceuticals as materials originating from the food chain but used in concentrated, functional, or specialized forms to deliver health-related effects. Prof. Sayeed Ahmad illustrated this distinction with the example of tomato versus lycopene-rich preparations: the food itself nourishes, while the extracted and biologically characterized component enters the nutraceutical space when safety and activity are demonstrated.

Nutraceuticals versus drugs

One of the strongest themes of the session was that nutraceuticals and drugs cannot be separated simply by asking whether both show biological activity. The more meaningful distinction lies in intended use, regulatory framing, target specificity, claim language, and the molecular architecture of the active system.

Dr. Prasad Thakurdesai noted that classical pharmaceuticals are often single purified molecules designed for defined targets with relatively high potency and selectivity, whereas nutraceuticals are usually multi-molecular systems that influence several pathways simultaneously. That multi-target behavior may make nutraceuticals valuable in chronic support, metabolic support, rehabilitation, performance, and quality-of-life applications, but it also makes their pharmacology harder to map through conventional drug-development logic alone.

Prof. Sayeed Ahmad added an important regulatory and conceptual nuance by distinguishing among food, nutraceuticals, and medicines, especially within Indian traditional systems. In the discussion, foods were positioned as primarily nourishing, medicines as intended for treatment, and nutraceuticals as health-supporting interventions that should not be positioned as disease-treatment products.

The shift from generic to mechanism-led claims

A recurring insight across the session was that the nutraceutical sector is moving away from broad, non-specific wellness language and toward sharper biological positioning. Dr. Thakurdesai stressed that the field is evolving from generic claims to more specific claims linked to systems, targets, and pathways, which makes pharmacological understanding increasingly central to product development.

Dr. Shalini Srivastava reinforced this point by observing that even familiar ingredients such as curcumin or ashwagandha may exhibit different pharmacological behavior when reformulated into liposomal or phytosomal systems. In practical terms, this means the industry can no longer assume that one ingredient name guarantees one pharmacological identity; formulation architecture now shapes exposure, interaction, and expected outcome.

Choosing meaningful endpoints

A major challenge raised by the moderator Dr. Balkumar Marthi was how to define endpoints for nutraceuticals when they do not fit the narrow target-and-receptor model of many drugs. The panel's response was both pragmatic and important: nutraceuticals still require targeted endpoints, but those endpoints should align with permissible structure-function claims and product-specific mechanisms rather than vague promises of "overall wellness".

Dr. Shalini Srivastava argued that the industry should move toward endpoints that are tangible and measurable, such as mobility improvement or enzyme induction, provided those outcomes support the claim framework and the product's mechanistic profile. This perspective has major implications for R&D design because it places pressure on formulation scientists, clinical teams, and regulatory strategists to define the endpoint before they define the claim, not the other way around.

Safety as a scientific discipline

Safety emerged as one of the most urgent themes of the event. While nutraceuticals are often perceived as inherently safe, the panel repeatedly challenged that assumption and argued that safety evaluation in this sector must become more structured, system-aware, and product-specific.

Dr. Thakurdesai emphasized that nutraceutical safety demands broad margins because these products are often self-selected by consumers rather than prescribed by physicians, increasing the importance of dose understanding and toxicological depth. He also introduced the idea that conventional toxicity packages may be only a starting point, and that "safety pharmacology" at intended-use conditions deserves far greater attention in nutraceutical development.

Dr. Shalini Srivastava extended this argument by calling for targeted safety plans tailored to each molecule or formulation, especially when a product may place stress on a specific physiological system such as the gastrointestinal tract. She also highlighted the absence of robust post-marketing surveillance in the nutraceutical sector, contrasting it with the large real-world safety databases that support pharmaceuticals.

Dr. Muneeb sharpened the message from an R&D toxicology perspective by pointing to the need for dedicated nutraceutical safety evaluation functions analogous to drug safety evaluation departments in pharmaceutical companies. That insight is particularly relevant for science-led companies because it reframes safety not as a late-stage compliance exercise, but as an organizational capability that should be built into discovery, formulation, testing, and claims development.

Identity, authenticity, and quality control

The regulatory discussion repeatedly returned to a core principle: poor identity control and inconsistent quality can distort both efficacy and safety interpretation. Prof. Sayeed Ahmad stressed that source authenticity, identity, and quality are foundational, especially when products draw on traditional systems where the plant part, preparation style, and history of safe use matter materially.

The panel cited multiple operational controls that should become non-negotiable, including authentication of the source material, stronger GMP execution, DNA fingerprinting where relevant, traceability across the supply chain, and tighter control of residual solvents, microbial burden, and adulterants. Dr. Shalini Srivastava also cautioned that adulteration in original extracts is damaging the industry's credibility and that stronger regulatory submission expectations would improve accountability.

Product-specific efficacy, not borrowed evidence

One of the most commercially consequential points of the session that Dr. Balkumar Marthi raised was the rejection of borrowed efficacy. The panel argued that a nutraceutical product cannot claim the efficacy of another company's material simply because both are labeled with the same ingredient name.

Dr. Shalini Srivastava explained that extraction process, solvent system, composition, and target application all influence efficacy, making proprietary or product-specific evidence essential. A curcumin developed for sleep support, for example, cannot automatically inherit the clinical logic of a curcumin positioned for mobility or another health area, because endpoint selection, mechanism, and formulation strategy differ materially.

AI, omics, and the next generation of R&D

The panel viewed artificial intelligence as a meaningful accelerator, but not a replacement for experimental and clinical rigor. Dr. Shalini Srivastava described AI as useful from concept generation to study design, including virtual analysis of datasets and sample-size estimation, while also supporting formulation work.

Dr. Thakurdesai and Prof. Sayeed Ahmad both positioned AI as especially promising for a field still defining its methodological boundaries. AI, omics, and network-level approaches may help researchers interpret complex extracts, predict pharmacodynamic or pharmacokinetic patterns, and explore regulatory data packages more efficiently, but the panel was clear that clinical validation remains the ultimate filter for acceptance.

The microbiome as the missing bridge

Perhaps the most forward-looking theme of the event was the role of the gut microbiome in explaining nutraceutical efficacy, safety, and pharmacokinetic behavior. The panel suggested that some of the apparent disconnect between observed clinical effects and poor classical absorption profiles may be resolved by understanding how gut microbes transform complex phytochemicals into secondary metabolites that later appear in circulation.

Dr. Shalini Srivastava described the relationship as bidirectional: a healthy gut can improve nutraceutical handling, and many nutraceuticals can in turn support gut health. Dr. Thakurdesai went further, proposing that the focus of nutraceutical pharmacokinetics may need to shift from the stomach-centric assumptions of synthetic pharmacology toward the gut microbiome as a dynamic mediator of both efficacy and safety.

This is not merely an academic thought. It opens a concrete R&D agenda around microbiome-linked PK/PD interpretation, metabolite tracing, tolerance assessment, and formulation strategies that consider prebiotic, probiotic, and postbiotic interactions more seriously than many current development programs do.

Regulatory direction and pathway thinking

The title of the session What's Your Pathway? proved especially apt when the discussion turned to regulation. The panel broadly agreed that the Indian nutraceutical landscape still needs clearer pathways for products that sit between conventional supplements and more rigorously documented natural health interventions.

Dr. Thakurdesai referred to models such as Australia's complementary medicine pathway and Canada's natural health product framework as examples of how lower-risk, evidence-backed natural products may be handled through defined regulatory categories without forcing them into either pure food or conventional drug structures. The discussion suggested that India could benefit from similarly thoughtful pathway development, provided that industry also accepts greater responsibility for substantiation, risk analysis, and quality compliance.

What the session means for nutraceutical R&D

For R&D scientists, the event delivered a clear strategic message. The future of nutraceutical pharmacology will belong to teams that integrate formulation science, mechanism mapping, safety pharmacology, quality-by-design, clinical endpoint discipline, and regulatory intelligence into a single development workflow.

Several practical implications emerge from the discussion:

- Product development must become pathway-aware, not merely ingredient-aware.
- Claims should be built from product-specific evidence, not inherited category narratives.
- Safety packages should reflect intended-use biology and likely system-level vulnerabilities, not just conventional toxicology checklists.
- Microbiome science should be treated as a central pharmacology question, not a peripheral marketing theme.
- AI can accelerate discovery and design, but cannot substitute for rigorous validation.

Closing reflection

By the end of the session, a strong consensus had formed: nutraceuticals are not "lighter drugs," nor are they simply upgraded foods. They occupy a scientifically and regulatorily complex middle ground that demands its own frameworks, its own methods, and its own discipline of evidence generation.

That is why The R&D Grail Episode-7 mattered. It challenged the industry to stop treating nutraceutical pharmacology as a borrowed language and start building it as a field in its own right—one grounded in identity, mechanism, safety, specificity, and translational relevance.



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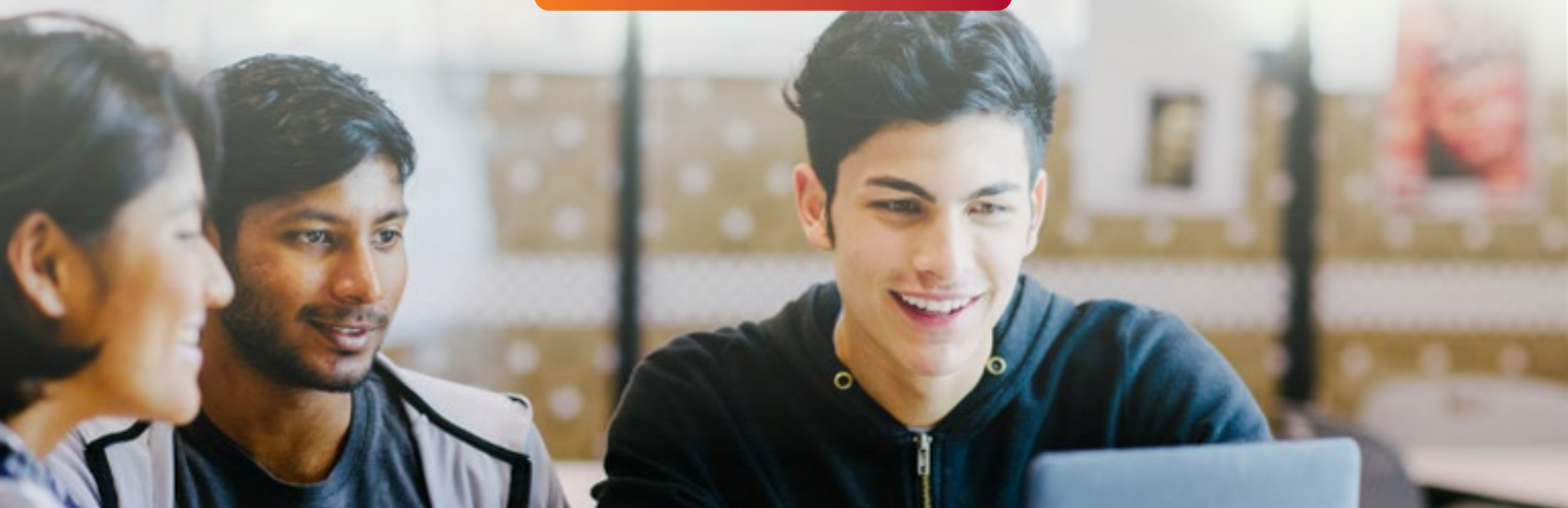
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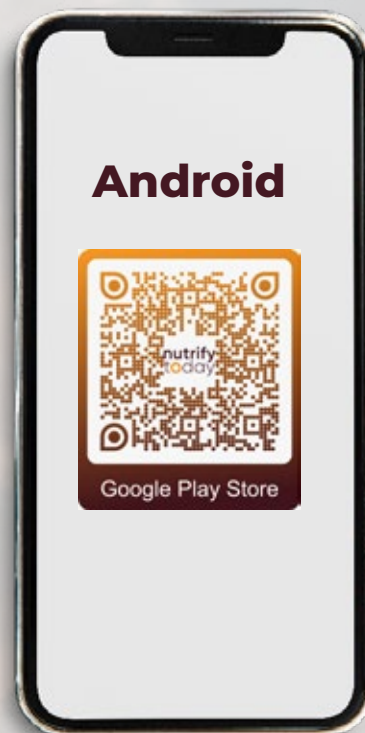
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