

# Exploratory Research Unlocks Product Potential

by Latesha Richards

An important part of any natural ingredient's sustainability and longevity lies in the discovery phase, where new ideas and opportunities are conceived. During this stage, sponsors can determine whether the ingredient is functional as a nutritious food additive, is clinically effective in a topical agent, and if the product will successfully target a different population, among other important considerations.

Unlocking a product's potential essentially begins with determining the commercial feasibility of the idea and then confirming a hypothesis with research. That research may be composed of published literature, but may require a method that will provide real-time, product-specific data. Four main activities can be used to unlock a product's potential:

## 1. Literature Research

First, the sponsor must assess if there is a strong case for pursuing studies to test for attributes or efficacy from peer-reviewed literature, previously conducted clinical trials and/or market research data.

Sponsors must also evaluate whether peer-reviewed literature on the ingredients alone is convincing enough to base a marketing message on, or if a product-specific trial is necessary. Sponsors must assess what the protocol designs were of those studies and how they were conducted to determine how statistically significant the data is.

## 2. Market Assessment

Information about markets, customers and competitors will reveal a product idea's potential in the given market. The marketing team should

ask questions such as: Does it make sense statistically to target this new market? Will this new application/delivery system be accepted by users? Will this new formulation be commercially viable in today's market?

## 3. Research Hypothesis

The sponsor must then come up with a hypothesis based on the expected outcomes revealed from the literature data that can be tested in a clinical study. Before a study is done, the sponsor must assess which potential clinical endpoints or definitive endpoints will be tested in order to test the hypothesis. The research question should be novel in that it has the ability to confirm or refute previous findings, extend previous findings or provide new ones, and be relevant to the new product idea and endpoints being tested.

## 4. Exploratory Clinical Efficacy Study

An exploratory clinical efficacy study is a pilot study that measures clinical outcomes of a product in humans. The hopeful outcome of this study is to demonstrate efficacy for purposes of making a quick assessment of the commercial potential of the product in the new indication, delivery system or market. The resulting data is then used to formulate a hypothetical structure/function claim, create a marketing message and to determine if there is enough evidence of clinical efficacy to warrant larger clinical trials.

The clinical efficacy study employs a targeted group of no greater than 100 subjects and short intervention/treatment period that will yield

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data in a relatively short time frame, depending on the number and type of clinical parameters measured. Studies can utilize a traditional randomized, placebo-controlled and/or blinded study design to test the product against a control. The exploratory clinical efficacy study begins to test human response to a single dose or escalating doses, which would be used to determine optimal dosing for future studies.

Potential clinical endpoints can be measured qualitatively by gathering responses from a small focus group about beliefs, feelings, opinions and perceptions about product attributes or efficacy.

For example, an ingredient manufacturer wants to target its proprietary amino acid blend and reformulate it as an energy beverage for the adult sports nutrition market. It decides to conduct an eight-week, 40-subject exploratory clinical efficacy study using a qualitative methodology and escalating doses. Efficacy at each dose can be ascertained qualitatively by asking athletes, "Did the test product help you feel speedier restitution of muscles?" "Did the test product allow you to increase training time?" "How long did it take for you to feel the effects of the product on your muscles?" These data will be helpful in determining an optimal dosage level for the sports nutrition market and give documentation to support a structure/function claim.

Clinical efficacy can also be measured quantitatively by performing various clinical tests. The type(s) of clinical testing varies from simple to elaborate depending on the clinical endpoint being tested, and the nature of the question posed by the sponsor.

For example, a beverage manufacturer wants to target its antioxidant green tea product to the weight-loss market. The beverage company wants to learn if pure green tea extract at a given concentration will have an effect on satiety in men and women wanting to lose weight, so it moves forward with a six-week, 50-subject exploratory clinical efficacy study to look at the effects of a single dose of green tea extract and its effect on satiety using questionnaires and quantitative metrics.

The sponsor can rate (qualitatively) the subjective satiety-related sensations before and after consuming the test product and/or measure the amount of food eaten after the test product using a Visual Analogue Scale or Satiety Index. They can also measure satiety using (quantitative) clinical tests such as the slow caloric drinking test, insulin sensitivity

measurement, meal tolerance, serum ghrelin (the hormone produced by the stomach that stimulates hunger) or serum leptin (the hormone that plays a key role in regulating energy intake and energy expenditure), among others.

If the exploratory study yields efficacy data and definitive endpoints that must be further tested, the sponsor can then decide to move forward to a formal Phase I study to further evaluate safety, the maximum tolerated dose, common adverse events, as well as pharmacokinetics and pharmacodynamics.

It is important that the exploratory research study is well-designed to provide unequivocal results. □

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