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THE VALUE OF EXPLORATORY RESEARCH

The expense of clinical research can be daunting to natural products companies, but exploratory research can provide early human and efficacy data, while limiting expenditures and complications of subsequent clinical studies.

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Abstract

Companies needing an affordable, flexible and fast way to begin looking at their product attributes can take advantage of an exploratory human study. An exploratory human study is a preliminary study used to test a product's attributes or effectiveness in a small group of humans. The study is flexible in that it can employ a quantitative (objective) and/or qualitative (subjective) design to measure desired effects or outcomes.

Depending upon the nature of the sponsor's question, the study can be designed to allow the sponsor to begin testing a product's/ingredient's clinical effectiveness and clinical impact in humans. This is referred to as an exploratory clinical efficacy study. This study uses a small study group to test responses to a single dose or escalating dose of the product/ingredient over a short intervention period. Clinical efficacy data is collected on potential clinical endpoints (anticipated beneficial effects of a product/ingredient on a specific condition). Clinical endpoints can be measured qualitatively by gathering responses about beliefs, feelings, opinions, and perceptions about product attributes or efficacy from a small focus group. These endpoints can also be measured quantitatively by collecting data from respondent-completed surveys or various clinical tests.

The study can be performed on any finished product such as a cosmeceutical, dietary/herbal supplement, functional beverage/food, or any single ingredient application for which a structure/function claim is made and some safety or Generally Recognized as Safe status has been established for the ingredient(s) used.

Performing an exploratory study is a powerful way to generate pilot human and efficacy data on any developing, new or on-the-market product or ingredient.



Clinical research is a very time consuming process that can get very costly. Many times, clinical trials can be challenging to design and execute, and early mistakes can cost a company more time and money than they bargained for. However, the need to test a product or ingredient is of increasing importance, as both consumers and regulators are demanding scientific substantiation.

Fortunately, there are approaches to clinical research that may help limit the costs. Conducting exploratory research helps minimize expenditures and complications during the clinical research process. It provides a flexible, affordable, and fast way for companies to obtain early human and efficacy data. It is also beneficial for those who are beginning the clinical research process. A flexible exploratory human study that consists of using quantitative and/or qualitative approaches would provide a great advantage.

An exploratory human study is a pilot approach used to determine if key attributes of a product exist in humans in order to establish a hypothesis or theory. The sponsor's (i.e. the Natural Products Company) goal is to get answers to questions about their product in the exploratory study. Preliminary data gathered from a small, but targeted group of individuals (usually between 20 and 100 per study) is then used to formulate the hypothesis.

An exploratory human study can be performed on almost any developing, new or on-the-market natural product for which some safety has been measured and/or Generally Recognized as Safe (GRAS) status has been established for its ingredients.

Quantitative & Qualitative Studies

It is important to understand and weigh the various research options available. Exploratory human studies are flexible in that they can employ a quantitative or qualitative design to measure a desired effect or outcome.

A quantitative study is a research methodology that uses statistical models to measure the actual observed outcomes from respondent-completed questionnaires, surveys or clinical tests.

A qualitative study measures observable effects or outcomes by gathering information about beliefs, feelings, opinions and perceptions about product attributes from a small focus group.

Both quantitative and qualitative methods can be used to assess non-clinical attributes such as taste, smell, color, or texture, e.g., flavors or cosmetics. These methods can also be used for assessing clinical efficacy.

Exploratory human studies can also be designed to measure clinical efficacy. An



exploratory clinical efficacy study measures outcomes of a product such as a cosmeceutical, dietary/herbal supplement, functional beverage, food or any ingredient application for which a structure/function claim is made. The study allows the sponsor to begin testing the product's effectiveness and clinical impact in humans.

The clinical efficacy study employs a small study group and a short intervention period that will yield data in a relatively short timeframe compared to large clinical trials. Intervention/treatment duration can be as little as one day or as much as one month. Studies can also be designed as a placebo-controlled or blinded study to test the product against a control.

The exploratory clinical efficacy study begins to test human response to dosing (either as a single dose or escalating doses) and other product/ingredient specific parameters. The data can provide useful information on how a product works and how to determine optimal dosing for future studies.

Clinical efficacy data is collected on *potential* clinical endpoints. Clinical endpoints are the anticipated beneficial effects of a product on the specific condition, such as hair growth, acne severity, blood glucose levels, satiety, etc. or any other effect the product is believed to have. Clinical endpoints can be measured qualitatively or (quantitatively) by performing

various clinical tests, depending on the type of product, and nature of the question posed by the sponsor.

For example, efficacy of an antioxidant-based anti-aging product on reducing dark circles under the eyes (a potential clinical endpoint) can be ascertained qualitatively by asking respondents "How long did it take for this product to reduce your dark circles?", "Do you feel younger?" or "Do you believe this product enhances your skin and beauty?" Efficacy can also be ascertained by clinical analyses using imaging, melanin and erythematic indices, dermal thickness, etc.

Similarly, in a study investigating effectiveness of a glucose maintenance product on weight control (a potential clinical endpoint), a clinical analysis of blood glucose levels and weight tracking can be done, in addition to asking qualitative questions such as "How quickly did you begin to lose weight?" or "Did use of this product help to reduce your cravings for sweets?" These analyses can help a sponsor narrow down definitive clinical endpoints that can be tested in a larger clinical trial.

In short, the exploratory clinical efficacy study provides raw clinical data, and, is thus a great way for a company to begin quantifying their product's effectiveness.



AN EXPLORATORY HUMAN STUDY IS
REWARDING FOR NATURAL PRODUCTS
INDUSTRY

Performing an exploratory study is advantageous for natural product sponsors. Sponsors benefit from the immense insight exploratory research gives and confidence knowing they have conducted evidence-based research on their product or ingredient.

There are a number of examples where an exploratory research approach is beneficial and rewarding for sponsors:

1. A natural products company that has not performed human research and is interested in obtaining human data on their product.
2. Sponsors who need preliminary data to support a structure claim or boost brand awareness.
3. Sponsors who need quick data, but have limited funds and/or are working under a very short timeframe.
4. Sponsors who want to save time and costs during the product development process and reduce error in future studies.
5. Sponsors who want to explore the idea of using an existing ingredient in a new application or different delivery system.

6. Sponsors who are looking to expand into another consumer market.

Whatever questions a sponsor might have, performing an exploratory study is a powerful, affordable and quick way to generate human and efficacy data. Data collected from an exploratory study can be useful for making formulation changes or product enhancements, augmenting marketing material, determining if a product/ingredient might be valuable in a different therapeutic category or market, and for powering longer phase I-II safety, tolerability and efficacy studies.

Utilizing a third party organization such as a contract research organization (CRO) to conduct exploratory research is also highly recommended. A CRO that offers this service can design and facilitate a custom-tailored exploratory program that will streamline product development operations. Partnering with an adept CRO also increases product integrity and decreases research bias.

Latesha Richards is marketing coordinator for Nutraceutical Medical Research LLC, a CRO. The company's RAPID FOCUS STUDY™ offers a flexible, quick and cost effective exploratory platform to test natural products and ingredients in humans. For more information, call (914) 220-8325. Richards can be reached at (914) 220-8387 or lrichards@nutraceuticalmedicalresearch.com.