Is Your Dietary Supplement Commercialization Plan On Target?

nutrasource

Pharmaceutical and Nutraceutical Services

INTRODUCTION

Clinical research has become a fundamental step in the development of a dietary supplement. Nutraceutical companies are investing more than ever before in clinical research to support health and marketing claims and to gain a competitive advantage in a saturated marketplace.

Clinical trial design is an often overlooked but incredibly important aspect of a successful development and market launch strategy. Many companies, tempted by the promise of quick market access and lower clinical research costs at the outset, cut corners during the trial design phase and fail to spend sufficient time on developing a strategic protocol that will ensure study integrity. The unfortunate reality is that this strategy has led to statistically indecipheral results, devastating costs and irreparable brand damage for dietary supplement organizations.

This whitepaper is designed to help dietary supplement companies build a strategic development plan that focuses on clinical trial design to meet the end goal: the product claim. By adopting certain key aspects of the pharmaceutical industry's clinical development solutions, including the use of adaptive design for claim substantiation trials, there is potential for greater rewards in terms of prolonged market access, the possibility of additional claims, further regulatory classifications and future development opportunities. Read on to learn specific strategies organizations can employ in order to get products to market efficiently, successfully and within budget.

IN THIS WHITEPAPER, YOU WILL LEARN:

- The importance of clinical trial design in claim substantiation
- Advantages of using a product development plan based approach
- How dietary supplement companies can benefit from adopting key efficiencies utilized by the pharmaceutical industry

BALANCING RISK AND REWARD: THE READY, AIM, FIRE APPROACH TO PRODUCT DEVELOPMENT

Companies developing new products typically face two main barriers to market launch: budget and risk tolerance. Historically, this has led to two extreme approaches to product development:

- The **'ready, fire, aim'** approach; and
- The **'ready, aim, aim, aim, aim, fire'** approach.

Ready = Planning Phase: What is the purpose of the project? Who will do it? What resources will be needed?

Aim = Design Phase: What will we do? When will we do it? In what order will we do it? Who will do each part?

Fire = Execution Phase: Performance of the actions initiated and designed in the 'ready' and the 'aim' phases.

The 'ready, fire, aim' approach leaves strategic thinking to hindsight. This high risk approach is taken in the hope of achieving the quickest possible reward. In this model, gaps and questions are often left to be filled in later, with the chance the product will reach the market more quickly. This approach leaves little opportunity to consider alternative strategies and may lead to suboptimal approaches, lack of awareness and understanding of regulatory risks, and potentially inadequately supporting the desired market positioning.

In contrast, the 'ready, aim, aim, aim, aim, fire' approach concentrates on too many targets in time-consuming development, and this is often as risky as the 'ready, fire, aim' approach. In the 'ready, aim, aim, aim, aim, fire' model, often too much time is taken for planning in order to "get it right." This may result in missing the target altogether, if enthusiasm for the initative waivers, or if the program is stifled due to regulatory rules and procedures. Thus, a great marketing opportunity may be missed, and a competitor could fill the market gap.

When considering dietary supplement development, there is a third, less extreme approach that is preferential: the **'ready, aim, fire'** model. With this approach, a clear direction of development, strategy and target are established. This approach allows Sponsors to methodically consider the characteristics of their product while maintaining flexibility in product development. The 'ready, aim, fire' model also offers greater rewards than the other approaches, as it provides the potential for prolonged market access, stability, the possibility of additional claims, additional options for market positioning, and the potential for additional regulatory classifications, as well as future development opportunities.

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THREE APPROACHES TO PRODUCT DEVELOPMENT

Ready, fire, aim | **Ready, aim, aim, aim, aim, fire** | **Ready, aim, fire**

The continued pressures placed on the supplement industry by the Federal Trade Commission (FTC) and politicians who have recently marred the dietary supplement industry are inadvertently challenging the nutraceutical industry to take this more optimal 'ready, aim, fire' approach.

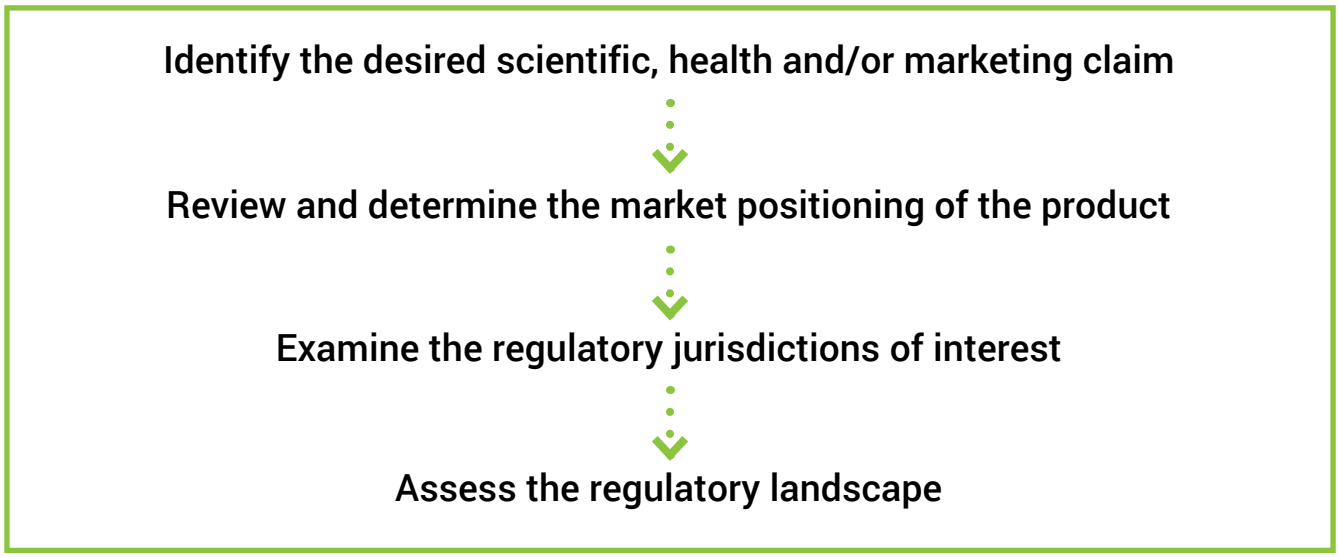
Done correctly, the 'ready, aim, fire' approach can be a realistic option for the nutraceutical industry. To be successful, Sponsors should adopt key lessons from the pharmaceutical industry with regards to product development and clinical study design. The following sections include an overview of strategic approaches to product development, the importance of strong clinical trial design, and key efficiencies adopted by the pharmaceutical industry so that dietary supplement companies can achieve success in the marketplace while ensuring a positive return on investment.

BRIDGING THE GAP BETWEEN SUPPLEMENT AND PHARMA FOR REGULATORY GUIDANCE AND CLINICAL DEVELOPMENT

There are many questions that must be asked and consecutive steps planned in order to successfully develop and launch a dietary supplement. What will the product to do? How safe is the product? Who will benefit from the product? How is dose determined? What else can be said about the product and is the evidence sufficient? What is needed to provide the evidence?

One of the biggest questions of all is: Where do I start? Supplement developers would benefit by taking a strategic, 'pharmaceutical-light' approach to product development. Always begin with the finished product in mind. Start by identifying how the product will ultimately be marketed and what the desired scientific, health and/or marketing claim will be. Next, review and determine the market positioning of the product. Third, examine the jurisdictions of interest. Do you want to launch the product in the United States? Canada? The EU? In multiple countries? Finally, assess the regulatory landscape. What steps need to be taken to get to gain access to your desired market? What gaps need to be filled in order to be compliant with the regulations?

ORDER OF STEPS IN PRODUCT DEVELOPMENT PROCESS



Working backwards from the product claim may sound simple, but it is a complex process requiring a great deal of strategic planning and regulatory forethought. To successfully build a solid development strategy, product development plans are key. This is an area that the pharmaceutical industry pioneered many years ago, after a number of compounds failed to achieve their clinical development goals. Sufficient time spent in the 'aim' phase, through the completion of a product development plan, can provide significant return on investment downstream, and avoid costly clinical work that may lead to confusing or contradictory results. Product development plans should review possible regulatory classification(s) of the product in the jurisdiction(s) of interest, assess current information about the product, evaluate the product-specific scientific evidence or, where this is not available, assess evidence on the same ingredients contained in the product of interest. A good development plan will identify gaps, risks and benefits along the pathway from conceptualization to market.

After any gaps have been identified, strategies must be developed to address deficiencies. For dietary supplements, the focus often needs to be placed on human clinical trials designed to substantiate both the marketing claims and any structure/function or health claims the Sponsor wishes to make. Jumping straight into a clinical trial without a detailed plan or roadmap can have devastating outcomes, including evidence unable to substantiate the desired claim(s), increased cost due to the need to repeat studies, strained relationships between Sponsors and institutions conducting the research, and delays in product launch. With such high stakes, a strategic approach to the clinical development of a product is imperative. Clinical development plans are a crucial investment for Sponsors in the dietary supplement space, as they transform the vision into distinct implementation phases and clinical studies, each with defined milestones and deliverables.

> "Sufficient time spent in the 'aim' phase, through the completion of a product development plan, can provide significant return on investment downstream and avoid costly clinical work that may lead to confusing or contradictory results."

FOCUSING ON CLINICAL TRIAL DESIGN FOR DIETARY SUPPLEMENT DEVELOPMENT

Clinical studies are typically discussed in terms of clinical trial phases, irrespective of product type. Depending on the Sponsor's goals, some clinical study phases may or may not be applicable to the program goals. This classic structure of clinical development is known as the fixed stage approach and includes four stages of research: Phase I, Phase II, Phase III and Phase IV studies. An overview of each clinical research phase is depicted on the following page.

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PHASE I STUDIES

Phase I studies include single- or multiple-dose safety and tolerability studies in the target population or in healthy individuals. Most common to the nutraceutical industry is the single-dose bioavailability study, which may be used to understand the characteristics of a single dose of product and its appearance in the blood, or to provide substantiation on a marketing claim in comparison with a competing marketed product. However, it is critical that nutraceutical sponsors to understand dosing of their product. A clinical trial may fail to show an effect, not because the effect wasn't there, but because dosing (the amount per dose, timing of dose and/or total dose per day) was wrong.

PHASE II STUDIES

Sponsors may begin development with a Phase II study, bypassing Phase I studies as evidence may be publicly available that pertain to the finished product's safety through toxicological studies and/or published human studies on the ingredients contained in the finished product. Less often does Phase II research include dose range studies.

Dose ranging and dose response studies are not commonly conducted in the nutraceutical industry but are key in the development of pharmaceuticals. Valid dose response data permit the determination of appropriate dosing and maximum recommended dose, while dose response studies elucidate appropriate timing of dose (morning versus evening) and frequency of dosing. A professional product development plan will identify the need for a dose range finding study or the ability to determine dose from existing data.

Phase II studies are often positioned as proof of concept (pilot) studies with the primary purpose to explore whether the product has clinical efficacy. Too often emphasis is placed on these studies as pivotal in providing statistical significance in a small number of subjects without understanding the characteristics of the study population, optimal dose, placebo response, and/or effect size of the product.

PHASE III STUDIES

Phase III studies are larger and often multi-center trials that confirm effects demonstrated in Phase II clinical trials. The need for Phase III trial designs is dependent on the findings of earlier stage trials as well as the necessity, dependent on the regulatory requirements, for the claims on the product.

PHASE IV STUDIES

By definition, Phase IV studies are post-marketing studies conducted to learn more information about the product after it is placed on the market. These include post-marketing surveillance studies and studies intended to support publications, but not changes to the label or registration changes.

In most cases, there is an insufficient understanding of dose-response. The dose-response is a key factor in avoiding rework of potentially efficacious products. Without an understanding of dose-response, there is increased risk for failure of pivotal trials due to selection of the wrong dose.

Study designs need to support the final marketing and scientific claims. Including proof of concept studies such as dose ranging or multiple dose studies, as well as pilot studies, prior to engaging in pivotal clinical studies warrants consideration in order to improve the chance of product success during clinical development. In addition, it may be appropriate in some cases to use an adaptive design.

In all clinical studies, measures of safety (adverse events, blood tests, etc.) must be included in order to characterize the safety profile of the product. However, collection of safety data should also be methodical, so that multiple study data can be combined in order to provide a product profile. Adopting these approaches can address the questions of what dose to use, what population responds best to the product, and—the ultimate question—is the product safe and efficacious? Without addressing this final question, there is a gap between the Sponsor and the regulator which can become a marketing barrier.

One of the difficulties faced during development of products using the classic 'fixed trial design' paradigm is that standard trial design only allows for minimal learning during the conduct of the trial due to the clear separation of trials into various phases. Applying such an approach leads to missed opportunities and delayed product development.

The pharmaceutical industry has identified this drawback to a fixed trial design and adapted it to better encompass a more robust trial design. It has become apparent that this design should be applied in nutraceutical research in order to reduce the risk of failure when Phase II studies are designed as a pivotal study, but do not achieve the endpoint. In these cases, the clinical development program may need to include additional early phase studies that can ascertain effect sizes and variability with the product of interest, in the population of interest.

Reflecting on the simple Phase I bioavailability study, how else could this design provide more information about the product? What effect does food have on taking the product? Does it reduce or increase absorption? What effect does a higher or lower dose have? Is there an increase or decrease in adverse events? How long does it take for the product to reach steady state in the blood? Can more information on safety or efficacy be gained in addition to absorption? Some of these adaptations to the common bioavailability study can be made to address these questions without having substantial impacts on costs, thus providing a greater understanding of the product and, in turn, greater return on the initial investment.

For example, it may be possible to investigate single dose and repeated dose bioavailability while extending the treatment period to assess time to steady state, as well as possibly adding some measures of efficacy to understand effect size and variability. Of course, to do so it is always important to ensure the integrity of the clinical trial design and resulting data. Therefore, the team involved in development of the protocol and management of the clinical trials must include qualified clinical and regulatory professionals, and a biostatistician familiar with this level of product development.

MAKING THE CASE FOR ADAPTIVE DESIGN IN DIETARY SUPPLEMENT CLINICAL TRIALS

There is also the potential to use a novel clinical program design recently introduced and accepted in pharmaceutical development: **adaptive design**. The FDA defines adaptive design in their guidance document, Guidance for Industry: Adaptive Design Clinical Trials for Drugs and Biologics, as "a study that includes a prospectively planned opportunity for modification of one or more specified aspects of the study design and hypotheses based on analysis of data (usually interim data)" (1).

While there has been much debate within the dietary supplement industry regarding adaptive design, the key to ensuring success is to follow the principle of 'adaptive by design,' meaning that they are prospectively planned and are not *ad hoc*, in order to maintain integrity and validity of the trial. When considering adaptive designs for pivotal trials, it can be a strategic advantage to engage the regulatory authority(ies) if the trial will be used as a pivotal study to substantiate claims. Most commonly, adaptive designs are referred to as adaptive randomization, group sequential designs, seamless phase designs (also referred to as adaptive seamless designs) and sample size re-estimation (2, 3).

Concerns from a regulatory perspective about adaptive design trials:

- The design should be appropriate to answer the scientific question of interest
- The Sponsor must demonstrate control of Power and Type I error rate over the entire clinical trial
- Operational bias could apply – therefore, appropriate pre-planning and measures are implemented to avoid operational bias (e.g., randomization, blinding, secure electronic systems, blinded steering committees, etc.)

To circumvent regulatory concerns, consideration and detailed methodology is required for the interim analysis, and a decision process is defined as follows:

- On what data will the adaptation be based?
- Who will see this data, and make the decisions?
- Will the results of this decision bias the trial?

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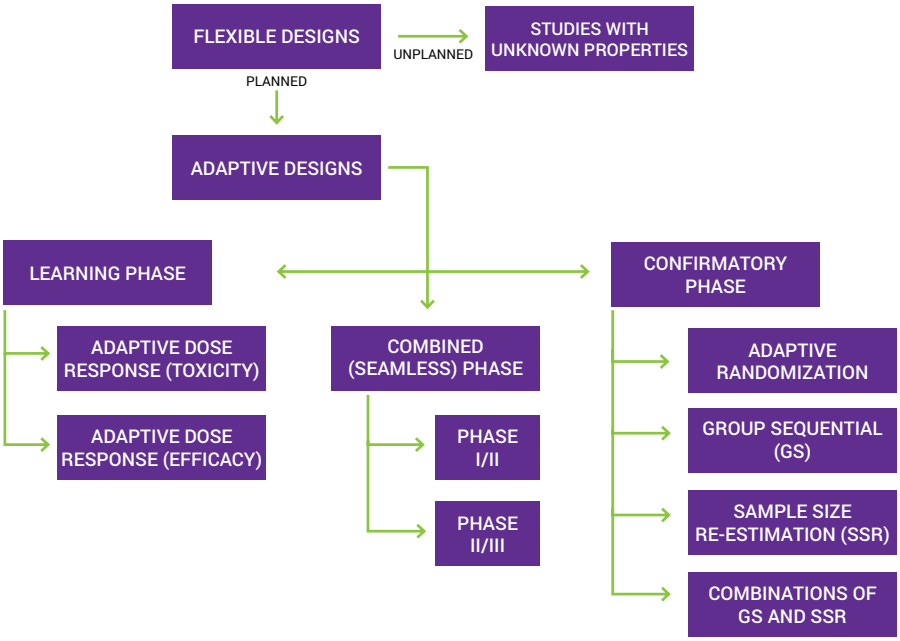

Figure 1 – Barriers and opportunities involved in adaptive trial designs (adapted from Kairalla et al., 2012) (4).

USING ADAPTIVE DESIGN TO ACCELERATE PRODUCT DEVELOPMENT

Clinical programs are confronted with many challenges due to the unpredictable and varied responses seen among subjects. Unlike animal models, where the laboratory animals are bred to be identical, humans are complex individuals, and health is based on a host of factors. How products are metabolized by individuals are not always fully elucidated. Sponsors must also contend with budget constraints and timelines, placing great pressure on trial success to provide maximum return on investment.

It is estimated in the pharmaceutical industry that only 1 of every 5,000 to 10,000 molecules make it to market, with a majority having poor safety profiles and therefore never making it past drug discovery and pre-clinical toxicology studies. Approximately 50% of new molecules that do proceed to clinical trials fail in the final stages of clinical research due to lack of efficacy (5).

Due to these astounding numbers and costs associated with such an inefficient model, especially with respect to later stage clinical research, the pharmaceutical industry has rethought adaptive design to help circumvent the issue of last stage failure. Historically, adaptive design was used in oncology studies as a mechanism to make decisions regarding the safety profile of drugs in this category. Through adaptive design trials, development efficiency is increased, because they avoid the need to repeat trials that fall short of reaching clinical endpoint goals. Avoiding the need to re-design a clinical development program provides significant cost and time savings.

Adaptive design trials allow additional study subjects to be added during the study in order to achieve statistical significance. Statisticians have come to a consensus that this is a viable model for clinical research as, historically, sample size estimates are based on literature and/or similar compound effects, and are not always reflective of the investigational product's actual effect size or the variability of the population under study. Specific statistical models are used and are planned for in advance of conducting a study in order to ensure robustness of the data and trial design.

In February 2013, a Senior Leadership Roundtable was hosted by Tufts Center for the Study of Drug Development (CSDD) to discuss adaptive trial designs in clinical research. Participants included a variety of executives from biostatistics, project management, clinical operations, and research and development, as well as representatives from the FDA and European Medicines Agency (EMA).

A definition of adaptive design consistent with current regulatory guidance was presented as follows: "Preplanned adaptations—generated through the use of trial simulations and scenario planning—of one or more specified clinical trial design elements that are modified and adjusted while the trial is underway based on an analysis of interim data" (6).

Simple adaptive trial designs include the pre-planned ability to stop a trial due to futility, most often used in pivotal Phase III studies to reduce costs associated with conducting a trial that has little to no chance for success. Another simple adaptive design is the pre-planned approach to sample size re-estimation. The value that sample size re-estimation provides is the ability to increase sample size during the trial which, in the dietary supplement industry, could be useful to improve success of a trial. Other adaptive trial designs which are used to a lesser extent may include adaptive dose-finding, seamless phase study designs, changes to randomization ratios and stopping for efficacy, among others.

The principle of adaptive design is to ensure a robust clinical trial design that provides the highest information value per resource unit invested. It allows for learning and decision-making in real time, facilitating the correct decision at the earliest time point and in the most efficient way. In the pharmaceutical industry, approximately 20% of all clinical trials use simple adaptive designs, with an increased use expected in exploratory clinical trials (6).

The concept of adaptive design trials has been debated in the nutraceutical industry over the past few years. There are arguments both in favor of, and opposed to, the idea, due to the spotlight placed on the industry by media, and a general increase in actions from the FTC with respect to claims substantiation. To understand the necessity and applicability of adaptive trials in nutraceutical clinical research, it is important to understand that the pharmaceutical industry recognizes this approach as an efficient process to reduce the cost of failure, due to lack of efficacy, during pivotal Phase II and Phase III clinical trials.

BEST PRACTICES FOR ADAPTIVE CLINICAL TRIAL DESIGN: THE RIGHT AND WRONG WAY

Utilizing adaptive design as part of a clinical research strategy can have many benefits. Adaptive trial designs can provide great cost savings to dietary supplement companies that adopt this approach. It is well known that regulatory agencies want to see a probability (P) value less than 0.05 for the primary endpoint in order to substantiate a claim. More often than not, the true effect size of the specific product under study and/or the variability in the change around the endpoint (including the placebo effect size) are not known, or merely estimated in a "best guess" manner.

Benefits of adaptive design strategies:

- Increased R&D efficiency
- Increased R&D productivity
- Increased probability of success
- More ethical

In order to alleviate this problem, and to obtain a solid sample size, it is desirable to apply an adaptive design to a Phase II or Phase III study. In such cases, a pre-planned sample size estimation by a blinded statistician (not the one who will conduct the final analysis) facilitates testing the assumptions and using data from the specific trial to recast the sample size requirement while maintaining the blind of the study. Of utmost importance is pre-specifying the analytical methods that control the type I error, identifying who will perform the interim analysis and how the interim analysis will be conducted, and providing justification for the application of the adaptive design. From a regulatory perspective, when planning a clinical study, interim analysis without realistic objectives should be avoided.

One of the most important questions that dietary supplement companies should ask in order to determine the need for an adaptive by design trial is: Is the outcome of the trial treatment comparable with that of the previous experience, or literature, upon which the specific trial is based? It is well understood that results of early phase clinical research, or research conducted by other researchers, may vary from later phase clinical studies, due to different patient selection, and may thus lead to failure of pivotal trials.

Despite the advantages of using adaptive design to avoid late stage efficacy failures, there remains some resistance to this strategy within the dietary supplement industry. Resistance to using adaptive design appears to be based on internal skepticism, as guidance from regulatory agencies does not appear to be a major barrier. Such barriers may include impact to budgets, delays in time, distribution of clinical supplies, data monitoring without introducing bias, lack of independent data monitoring groups and lack of experience in conducting adaptive trial designs. Although these are valid concerns, choosing a research partner who understands the nuances and proper use of adaptive designs mitigates these risks.

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There is a consensus among statisticians on the importance and proper use of adaptive trial designs and regulatory agencies are increasingly receptive to adaptive trial designs, in order to avoid unnecessarily conducting or repeating clinical trials. An interim analysis, or early examination of the data, introduces the possibility of damaging the integrity of the trial. Thus, adaptive design trials must be planned, conducted and controlled carefully. The following questions should be asked before using an adaptive design:

- Is there a need to perform interim analysis?
- Is the number of interim analyses justified?
- Is the information flow carefully described and controlled?

It may be attractive to some companies to have an interim look at the data to see how the project is progressing and/or whether significance has already been reached. This can be detrimental to the integrity of the trial. First, the Sponsor should never be involved in the interim analysis. Second, while it may seem attractive to stop a trial due to achieving statistical significance on the primary efficacy endpoint when an interim analysis is conducted, regulatory bodies warn against this, stating that the "primary efficacy data should be complemented by a careful assessment of consistency of trial results beyond the primary variable(s), including results in important subgroups, and the adequacy of the safety database" (7).

It is important to note that an interim analysis is not only pre-planned but restrictive in what will be reviewed. Typically, only the data required to determine if the adaptation is necessary will be reviewed, and only a recommendation will be provided. It is not intended to provide the Sponsor with interim results and statistics, as this can jeopardize the blind and overall integrity of the study.

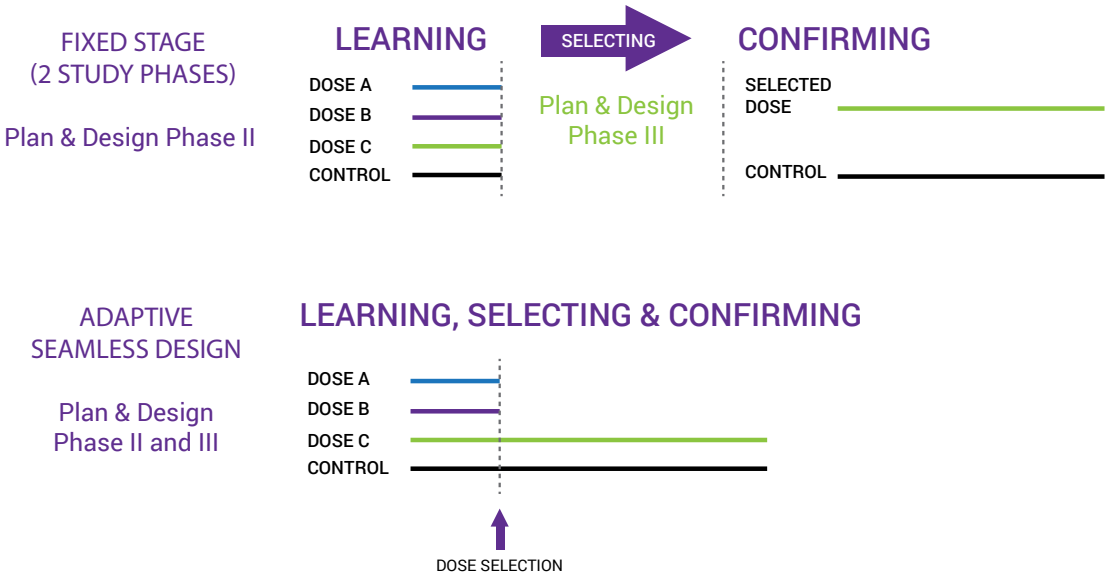


Figure 2 - Comparison of Adaptive Seamless Design for Treatment Selection with Separate Phase II and Phase III Trials (8).

SUMMARY

Many pressures are placed on dietary supplement product development, whether it is the need to be first to market, the desire to be innovative, or financial constraints. Proper planning and strategic thinking can lead to efficiencies downstream. To achieve this, it is important to always start with the product's label and claims in mind. To define the ultimate product goal and associated claims, there needs to be an understanding or a plan to complete the necessary information required to answer the important questions: what do you want to say about the product (both scientifically and from a marketing perspective), where do you want to sell the product, and what is the product. Thinking through these questions and developing a strategy to fill in gaps is critical in gaining downstream efficiencies.

Spending sufficient time to properly design clinical programs and each individual clinical study protocol is critical to expediting the process and minimizing the cost of failure during development of a dietary supplement. Ample time should be allocated to developing protocols that will ensure integrity and robustness of design, in order to provide valuable information to address the question being studied.

Focusing on dose response in early phase clinical trials is important to maximize the potential for success of the product in pivotal studies. Study designs, including dose response, also have the ability to provide additional information regarding the variability within the population under study, and this can provide values that can be more predictive of the actual sample size required to achieve statistical significance in a pivotal trial. In addition to the need for more investigation on dose response and selection, adaptive designs offer advantages that may warrant consideration in the clinical development pathway, in some cases.

Adaptive designs are increasingly becoming more popular in product development due to an awareness and understanding of their need to efficiently determine efficacy of a product. The planned, flexible study designs originating from the pharmaceutical model have the ability to direct the supplement industry's attention to promising assets, and may increase information value for the money invested. This is especially true in a resource constrained industry. The pharmaceutical approach to study design will also engage clinical, biostatistics, regulatory, project management, clinical operations and marketing aspects to unite and work toward a similar goal: market access with a quality, safe and efficacious health product. What adaptive designs will not provide, of course, is efficacy for a product which is not efficacious. Therefore, it should not be used in all cases.

Is your dietary supplement commercialization plan on target?

Our experienced team will help you develop a strong development and clinical research strategy that meets your goal while guiding you through the complex and often challenging regulatory framework.

Hit your target.

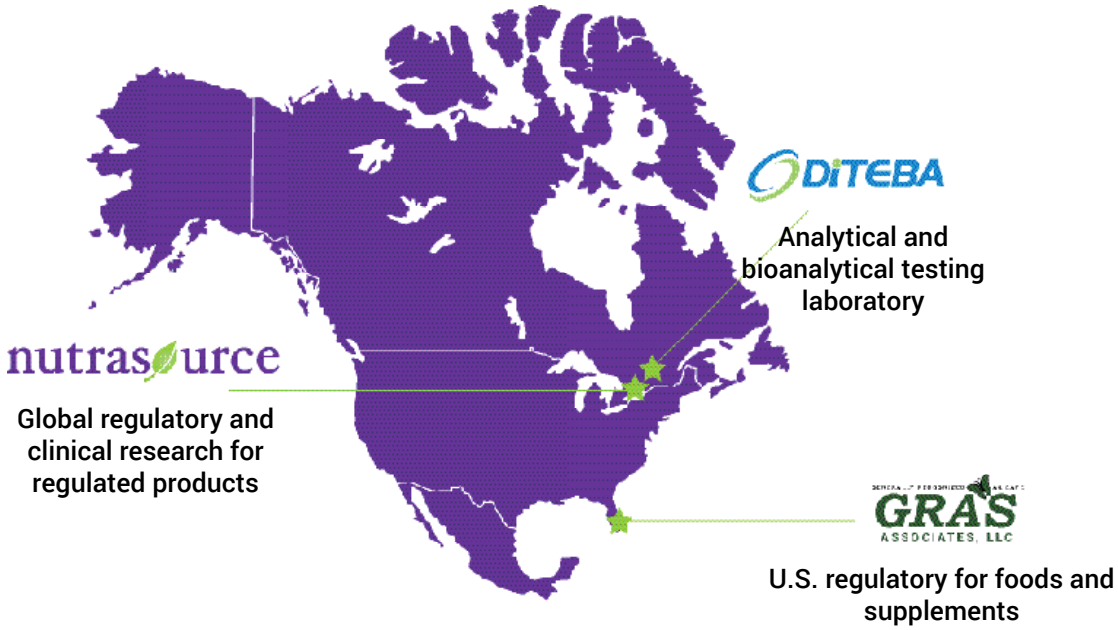
Contact our clinical development team today at info@nutrasource.ca to discuss your project, or click the button below.

ABOUT NUTRASOURCE

Established in 2002, Nutrasource is a full service contract research organization (CRO) specializing in navigating complex regulations on behalf of dietary supplement companies. With locations across North America, our experienced team partners with Sponsors to bring products to market through strategic product development, regulatory and clinical trial consulting, management and execution. Services for the dietary supplement and health products industry include:

- Product development strategies
- Pre-clinical program design and management
- Multi-center clinical trial management
- In-house clinical trials
- Regulatory consulting
- Claims substantiation
- Vendor management
- CMC support
- Product analytics
- Bioanalytics

For more information about our research, regulatory and clinical services, visit www.nutrasource.ca or contact us at info@nutrasource.ca.



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Mr. Baisley joined Nutrasource in 2013, bringing over 10 years of quality assurance, clinical and regulatory natural health product experience and an additional four years of antibody research with a primary focus on pre-clinical development programs for type I diabetes. Throughout his career, Josh has complied over 50 clinical trial applications for natural health products, drugs and veterinary products, representing over 10% of all applications received by Health Canada's Natural and Non-Prescription Health Products Directorate (NNHPD). Working closely with Health Canada since regulations were enacted in 2004, Josh participated as an invited member on Health Canada's Canada Vigilance Expert Working Group.

Josh's experience in regulatory submissions and clinical trial design extends from single ingredient and multi-ingredient dietary supplements including enzymes, probiotics, botanical extracts, vitamins, minerals and essential oils to combination dietary supplement / drug products. His experience with therapeutic indications include cardiovascular, cognitive function, detoxification, gastrointestinal health, hypertension, diabetes and pre-diabetes, men's health, women's health and weight loss among others.

JENNIFER ELLIS, B.SC., DIRECTOR OF CLINICAL & REGULATORY OPERATIONS

Ms. Ellis joined Nutrasource in 2012 with over 25 years of pharmaceutical regulatory and clinical experience. Jennifer has had tremendous success in identifying the preclinical and clinical requirements to take a product from concept to final approval in the fastest and most economical fashion. In addition, she has completed IND, CTA, NDA and NDS submissions in oncology, dermatology, cardiology, endocrinology, biologics, ophthalmology and medical devices.

RODNEY BUTT, M.SC., MBA, VICE PRESIDENT, REGULATED PRODUCTS DIVISION

Mr. Butt joined the Nutrasource team in 2011 with 25 years of experience in drug development, clinical operations, quality assurance and project management in both pharmaceutical and contract research organizations. His impressive resume includes global clinical development of multiple cardiovascular molecules and developing product infrastructure for clinical trials with enrollment from 30 to 700 subjects. In addition to providing logistical support for international trials, Rod has managed up to 15 operating clinical trials site simultaneously.

In his current role at Nutrasource, Rod is spearheading the design and implementation of process and infrastructure for the global development and approval of natural health products as prescription pharmaceuticals.

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