



Minnesota Diet Research Center

www.alimentix.com

9445 Minnetonka Blvd, St. Louis Park, 55426



Alimentix is a comprehensive clinical investigation center dedicated to conducting research and clinical trials for foods, ingredients, dietary supplements, natural products, low risk medical devices and drugs. Alimentix evaluates products to substantiate any “health effect” claims by independently conducting timely, scientifically designed clinical trials at a reasonable cost.

Claim substantiation is required for product manufacturers and businesses using health effect, structure-function and end-user claims for marketing. Claim substantiation helps to satisfy both stringent regulatory requirements as well as savvy, knowledgeable consumers. The risks of making a claim which has not been clinically tested may result in poor market acceptance, product recalls, or irreparable harm to a company’s reputation.

At Alimentix, we offer our comprehensive background in clinical, regulatory and quality affairs. We have the knowledge and expertise to conduct clinical studies and human use investigations. Alimentix’s specific experience includes developing detailed study protocols, designing customized diets for food product comparisons, creating customized questionnaires, monitoring studies, conducting statistical analyses and assisting with study publishing.

With thousands of new products brought to the marketplace each year, the demand for centers like Alimentix is increasing. The need to substantiate health claims with scientifically well-tested data and to communicate this information clearly and accurately in a truthful and not misleading manner to scientists, regulators and consumers is steadily increasing. Alimentix is poised to fulfill this growing need by providing comprehensive, high quality, rapid and cost effective clinical research for food, ingredient, dietary supplement, natural product, low-risk medical device and drug trials.

We look forward to being a part of your next endeavor!



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Clinical, Quality and Regulatory Affairs

Alimentix strives to be the leading clinical research investigative center for foods, food ingredients, dietary supplements, natural products, over the counter pharmaceuticals, and non-significant risk medical device products. We excel by providing innovative, cost effective and increasingly virtual options to complete research with speed and accuracy in order to enable our clients to market their products with appropriate clinical data and regulatory documentation supporting all claims.

Clinical Affairs

Trial Preparation:

- ☑ Protocols and Customized Diets
- ☑ Informed Consents
- ☑ Case Report Forms

Study Start-Up:

- ☑ Clinical Study Training
- ☑ Trial Registration
- ☑ Subject Recruitment

Study Execution:

- ☑ Monitoring and Data Collection
- ☑ Statistical Analyses
- ☑ Adverse Event Reporting

Study Closure:

- ☑ Clinical Report Writing
- ☑ Regulatory Submissions
- ☑ Product and Publication Support
- ☑ Quality Audits

Quality Affairs

- ☑ SOP Development
- ☑ Work Instructions
- ☑ Forms
- ☑ Risk Management

Regulatory Affairs

- ☑ Claim Substantiation
- ☑ GRAS Panel Meetings
- ☑ New Dietary Ingredient Documentation

Case Study – Safety Reporting for Dietary Supplement

Need: Large, global company required post-market surveillance of all safety reports for their new dietary supplement food product (first in class; new brand).

Approach: Alimentix team developed a system to track all adverse events (AE) and communicate results and established a specialized call center to log, categorize, track and report all AE calls using downloadable access. These actions provided monthly reports and multi-year comprehensive safety overviews that helped to developed individual categories and statistical trends analyses.

Value: Alimentix provided subject matter expertise and improved productivity of corporate team. Novel scientific observations were recorded in real time which lead to comprehensive summaries and reports for submission to the FDA or others to meet new safety reporting requirements



Focus Areas

- ☑ Finished Foods
- ☑ Functional Ingredients
- ☑ Food Supplements
- ☑ GRAS Dossiers
- ☑ Taste Studies
- ☑ Human Factors Engineering/Use Studies
- ☑ Satiety Studies
- ☑ Medical Devices (low risk, non-complex)
- ☑ Pharmaceuticals (low risk, OTC)
- ☑ Label Comprehension Studies
- ☑ Monographs

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