



WE SERVE INNOVATION

## Biofortis Global Locations

Biofortis is Merieux NutriSciences' global research organization supporting innovation in food, nutrition, health, cosmetics and consumer goods.

- Addison, IL (USA)
- Nantes, France
- Shanghai, China



## Biofortis Clinical Research

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# Biofortis Innovation Services

## Contract Research Services

Biofortis Clinical Research has been conducting clinical trials and consulting in the nutrition and dietary supplement arena for more than a decade in both the USA and Europe, completing over 300 studies as well as multiple scientific literature assessments. Our experienced research team can guide you through the entire clinical research process – from study strategy and clinical protocol development – all the way to the final study report or a manuscript publication.

## Types of Studies

- Safety, Tolerance
- Proof of concept
- Label / Claims Support
- Bioavailability / PK
- Feeding trials

## Services combined with site only services include:

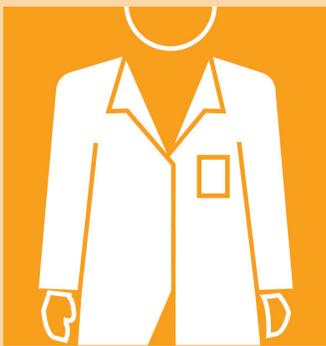
- Clinical trial design
- Clinical trial conduct
- Management of multicenter trials
- Statistical consulting
- Population database investigations
- Scientific writing

## Extensive Experience in:

- Nutrition clinical research studies on food products, ingredients and dietary supplements
- Multi-center clinical trial coordination including sites in Europe
- Lower than average screen fail rates due to our rigorous pre-screening methods and database data collection
- High subject flow clinic with over 5,000 visits per year
- Flexible team with unparalleled speed of study execution to data delivery

## Recruitment

- Robust database of clinical trial interested subjects collected over the last decade
- Free health screening including fasting lipid profile, blood pressure, weight, height, waist, and blood glucose testing
- Social media savvy recruiting tools (Facebook, Pandora, LinkedIn, Twitter, Google +)
- Digital display advertising with Chicago Tribune
- Ad placement in local community colleges and physician offices
- Access to more than 50,000 college students within a 10 mile radius
- Community outreach programs (local health fairs, presentations at local retirement communities, local physician referrals)
- Established vendor relationships with local women's health providers and radiology specialists



**Visit our website to access overviews and outcomes of some of our recent studies, see our new publications and subscribe to our quarterly e-newsletter.**

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## Provident Clinical Trial Unit

With our experienced clinical, subject recruitment and medical staff, the Provident Clinical Trial Unit (CTU) stands ready to meet the needs of academic and hospital-based investigators who have specific protocols they would like to complete in a rapid yet professional manner. We can complete studies before other institutional CTU have even finished the contracting phase. With metric based invoicing, you pay for the study as it is completed. This service is perfect for researchers eager to complete exploratory or confirmatory studies.

Our clinic is geared to handle pharmaceutical clinical trials for Phase II-IV clinical trials as well as nutrition intervention studies. In the past year, we've participated in 11 pharma studies, including diabetes, diabetic neuropathy, gout, lipids, sexual health, and cold sore. We offer an experienced research staff that assures maximum efficiency in all aspects of clinical research and delivering high quality research data in unmatched speed.

## Facility

Our facility has been specially designed with clinical trial research and subject convenience in mind. This dedicated setup allows staff to maximize both participant schedule flexibility and convenience as they participate in important research opportunities.

### Space and Equipment

- Dedicated research clinic (approximately 10,000 sq ft) with private exam rooms, full laboratory processing services including refrigerated centrifuge and fume hood
- GE Prodigy dual-energy X-ray absorptiometry (DXA) for measurement of body composition, including visceral fat measurements and bone density
- Dietary intervention services including metabolic kitchen for product preparation and group meals
- Portable electrocardiograph machines (ECGs), defibrillator (AED unit), and automated blood pressure machines (ABPMs)
- High security ultra low temperature freezers (-20°C and -80°C)
- Locked and limited access drug storage room
- Carbohydrate metabolism testing (insulin sensitivity and secretion)
- Cognitive function testing laboratory, 14 seats
- Point of care testing for fasting lipids, glucose, glycosylated hemoglobin
- Other equipment including: Quantum II Bioelectrical Impedance Analyzer (provides body composition estimates based off of electrical characteristics), complete exercise physiology laboratory, EndoPAT laboratory
- Clean and spacious facilities for monitor visits

## Non-Clinical and Consulting Services

Biofortis scientists are available to support your project with a range of non-clinical services. We can provide proprietary research reviews, commentaries, manuscripts and consulting to support the nutrition, food and supplement industries. We also offer data management services including data collection and export. Our biostatisticians can apply their specialized skills to analyses of data from many areas such as observational studies, R&D, laboratory method validation, genomics and more.

### • Literature reviews:

- Evidence mapping
- Systematic review (qualitative)
- Systematic review with meta-analysis (quantitative)
- Proprietary reviews including white papers, regulatory dossiers

### • Statistical Consulting:

- Study design: sample size and power determination
- Literature-based "state of the art" statistical analysis plan
- Clinical programming using SAS
- Quality audit of statistical analysis and programming
- Data interpretation: statistical methods and write-ups for publications/presentations

### • Clinical Data Management:

- Electronic or paper CRF development
- Database design: 21 CFR Part 11 compliant
- Data management: data entry, monitoring, query, cleaning, and export