NutraClinical, Inc.

Discover what your product can do clinically

Clinical Studies

Background

NCi
NutraClinical, Inc.

Experience

NCI's founders bring decades of research and management experience from the biopharmaceutical industry, applying their knowledge and expertise to the rapidly evolving functional foods industry.

Reliability

We have adapted the tools and strategies from Pharma to the entrepreneurial needs of the nutritionals industry. NCI has developed proprietary biomarker-based protocols and near-shore operations strategies to reduce costs, improve turnaround times and deliver scientifically and market-relevant value to our clients.

Value

Our goal is to help propel the functional food and nutritional supplement industry beyond the challenges of clinical testing by offering high impact, high quality clinical research services with unmatched affordability.

Expertise

Staff

NCI's employees are experienced and qualified with strong backgrounds in science, clinical and project management. Continuous training is provided to enhance specific knowledge and promote teamwork.

Service

NCI's provides comprehensive clinical research designed to elucidate and substantiate health benefits of functional foods and supplements. We can help demonstrate the benefits of your product, via validated clinical and experimental markers. Whether you are looking to place a single study or a complete development program, we have the experience and resources to move your program forward. Over the years we have studied dozens of novel products, giving us the knowledge and experience required to review new products with judgment based on solid foundations.

Philosophy and Approach

Quality

GLP or GCP like procedures and processes as appropriate, guaranteeing quality in all aspects of our business.

Communication

The latest technology is used to communicate with you. Progress updates can be made by e-mail, teleconferencing, videoconferencing or face-to-face meetings, all of which can be scheduled at agreed frequencies and with appropriate attendees from your team and ours.

Forward thinking

There is continued investment in staff development and training.
We constantly review where we are and look to the future, responding to the evolving needs of our clients and the regulators, to ensure that we maintain our position at the leading edge of function food clinical research.

Proposition

Our clinical studies are designed to bring value to your product development and marketing efforts. We assist you in evaluating or identifying bioactivity areas that are relevant to consumers and the industry. Our standard study designs aim to provide the most bioclinically relevant data in the shortest time possible and at the lowest cost.

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CLINICAL STUDY PACKAGES

	25K Fast Track Clinical Studies	35K Fast Track Extended Clinical Studies	45K Target Open-Bio Clinical Studies	65K Target Spec-Bio Clinical Studies
Subjects	12	12 to 24	12 to 24	12 to 40
Subject Condition	Healthy	Healthy or Preconditioned	Healthy or Preconditioned	Healthy or Preconditioned
Study Days	1	1 to 28	1 to 56	1 to 56
Time Points	5	5 to 15	5	5 to 15
Target Condition (One to Chose From)	Energy VAS	Energy VAS	Energy VAS	Energy VO2 MAX
	Satiety VAS	Satiety VAS	Satiety VAS	Satiety VAS
	Dose Assessment Energy	Pain VAS	Pain VAS	Pain VAS
	Dose Assessment Satiety	Inflammation CRP	Inflammation CRP	Inflammation ORAC-CRP
		Dose Assessment Energy VAS	Glucose Control	Glucose Control
		Dose Assessment Satiety VAS	Sports VO2MAX	Sports VO2MAX
		Dose Assessment Pain VAS	Dose Assessment Energy VAS	Dose Assessment Energy VAS
		Dose Assessment Inflammation CRP	Dose Assessment Satiety VAS	Dose Assessment Satiety VAS
			Dose Assessment Pain VAS	Dose Assessment Pain VAS
			Dose Assessment Inflammation CRP	Dose Assessment Inflammation CRP
			Dose Assessment Glucose control A1C	Dose Assessment Glucose control A1C
			Dose Assessment VO2MAX	Dose Assessment VO2MAX

High impact, high quality clinical research services with unmatched affordability

*Estimated costs are in US Dollars. Pricing may vary with specific study design.

Experience

We have considerable experience in the clinical evaluation of food based products. To the date we've completed more than 40 studies. The table below provides a partial list of the study types we have conducted on behalf of clients:

- **obesity**
- **weight management**
- **appetite control**
- **diabetes**
- **cardiovascular disease**
- **bowel health**
- **vascular disease**
- **bone health**
- **inflammation**
- **energy enhancers**

Study Models

Acute Dose Response Studies: T-MED protocols have been designed for supplements and food based Products where no previous studies have been conducted. Assessing a True Minimum Effective Dose is a critical part of the product development puzzle. It is also well known that lower doses can have the same effect or better than higher doses. A True Minimum Effective Dose will reduce costs and potential side effects.

ATP & Mitochondrial Studies: Mitochondria are a cells' "powerhouse" that produce the ubiquitous energy currency (ATP) by consuming oxygen, producing water and building up the proton motive force. Oxygen consumption is a classical means of assessing energy expenditure, one component of energy balance. Mitochondrial activity plays a central role in many metabolic tasks. Our Energy Protocols are designed to correlate the mechanisms of action for products intended to increase energy, in regards to the mitochondrial function.

Glucose Control Booster Drinks: If your product is intended for glucose control, our DB protocols will help you to elucidate its benefits. NCI can accurately evaluate the efficacy of your product using A1C, insulin resistance and other relevant biomarkers to monitor prescreened and preconditioned prediabetic subjects.

Cytokines Functional Status Studies: NCI is revolutionizing longevity-enhancing research in nutraceuticals with biomarker based SIRT AGING protocols with valuable biomarker data. We provide the most comprehensive aging discovery arrays and hormonal profiles.

Studies have shown that changes in hormone level can be detected years prior to accelerate aging. A complete panel of blood targets and biomarkers including MPO/Chlorination, SIRT1/mTOR are employed to test acute or extended treatment products.

Pain and Inflammation Trials: Using the most advanced technology NCI brings Osteo Arthritis Imaging based protocols, biomarkers and subjective measurements such as WOMAC® and other VAS questionnaires. QA Protocols will help you to define the role of your product in relieving pain and inflammation due to Osteoarthritis.

If your product is intended to improve full use of joints, take advantage of the QA studies to elucidate your supplement benefits.

Study Models

Energy Products: Put your product to the test using our new VO2Max protocols. These protocols are designed to measure accurately the benefit of supplements created to improve performance for many disciplines like running, cycling, rowing, swimming etc.

Using real athletes with specific VO2Max scores and State of the Art facilities your product will now have validated data for Aerobic Threshold (AeT), Anaerobic Threshold (AT) and VO2Max testing.

Appetite and Weight Control Trials: Any client with supplements intended to manage obesity, will find in our OB protocols the most accurate biomarker solution to elucidate the potential benefits for their products designed to suppress appetite or manage weight loss.

Clients can find a broad range of selective criteria for every specific product. Complete routine analyses are performed on each study and more complex analysis can be selected according to the nature of the product.

Cognition Intelligence and Behavior: Although the task of cognitive neuroscience is to describe how the brain creates the mind, historically it has progressed by investigating how a certain area of the brain supports a given mental faculty. In other words, for most of its history, the biggest question of cognitive neuroscience was "Where?".

Combining neuroscience and its technologies with cognitive science and its entire interdisciplinary field, we're able to bring you protocols designed to assess cognition and brain function and to define the mechanism of action of any supplement intended to improve those factors.

Acute and Chronic Sinusitis Studies: Complex and accurate CT protocols are used in extended studies to measure sinusitis.

We employ CT Scans to evaluate these classes of supplements. Imaging is now an active component when measuring acute and chronic sinusitis. We use this and other objective methods such as biomarkers and blood targets to bring value to your product by finding its range of effectiveness.

Diagnostic

Tests and Capabilities:

- Clinical Marker Assays
- Blood cell gene profiles
- Serum enzyme activity (CETP, PON1, Elastase, MP)
- Subjective measures (WOMAC, McGill, and other)
- Complete Blood Counts
- Clinical Chemistry
- Blood Bio-Markers (Isoprostanes, CRP, Cytokines, Chemokines)
- Serum biomarkers (Isoprostanes, Interleukins, Chemokines, CRP)
- Serum metabolites (Glucose, LDL, oxLDL, HDL, Triglycerides)

Technologies:

- Gene Profiling
- Cytokin and Chemokine Profiling
- Protein Profiles
- Oxygen and Energy Metabolism
- Using direct and real time techniques
- CT Scan
- X-Ray
- MRI/FMRI
- Adult Stem Cells

Project and Program Management

Study Team

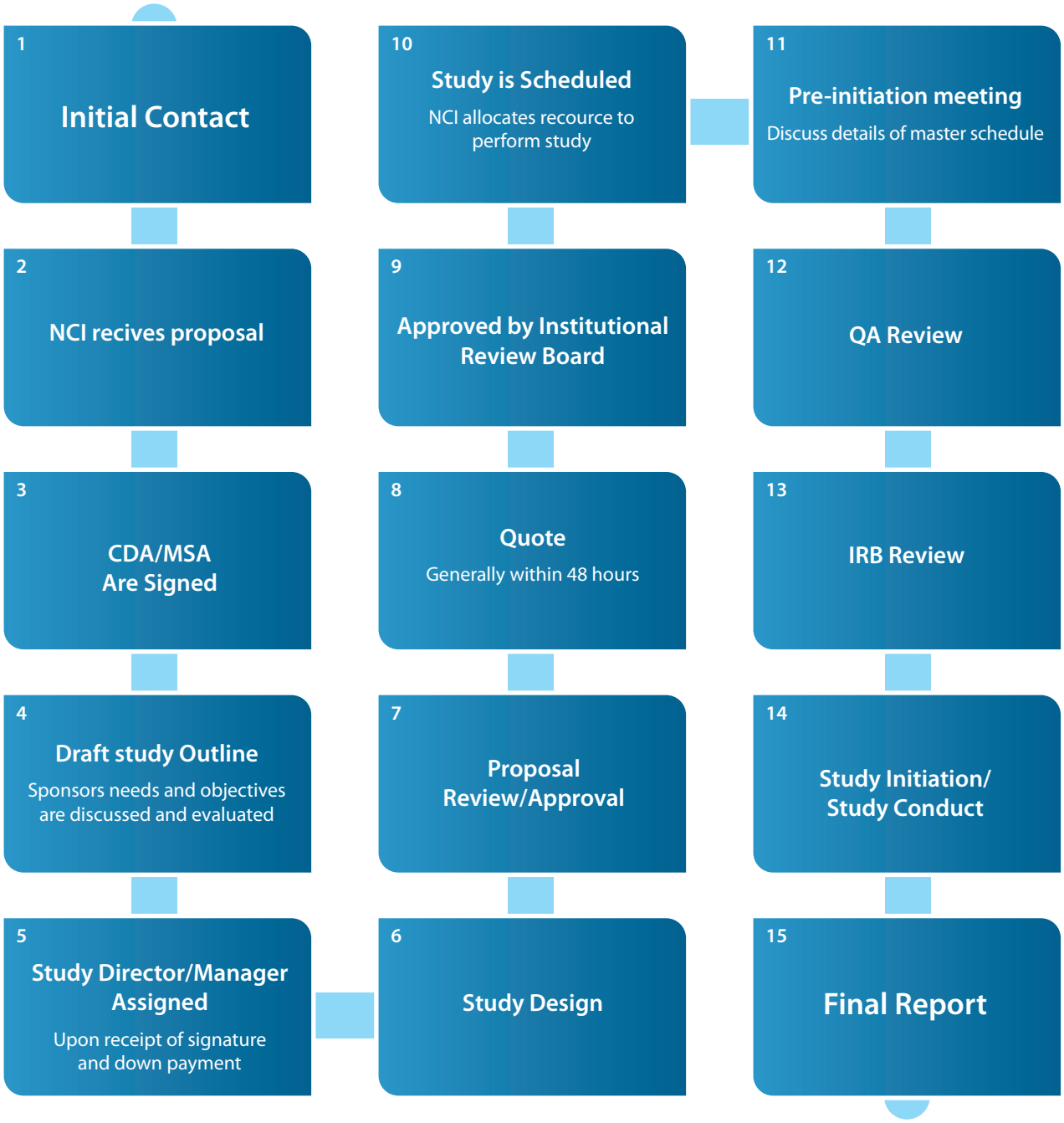
All studies are conducted by our unit and are allocated a project team which is responsible for the running of the study; a typical team consists of:

- IRB (Institutional Review Board)
- Principal Investigator (medical director, medical advisor, senior physician)
- Study physician
- CRA (usually assigned the role of project manager)
- 2 study support personnel
- Pharmacists
- Statitician
- QC/QA Personnel

The project manager is responsible for overseeing the project, making sure that the timelines are met and that communication with the client is optimal. Multidisciplinary team meetings occur before and during the study, between the project team and representatives from relevant clinical support areas including data management, statistics, QA, clinicians and bioanalytical chemistry.

All aspects of the study are discussed including timings, interactive data management, coordination of results and study reporting. Communication between client and project manager is vital to the success of the project. NCI's strives to ensure that this is optimized through internet access, teleconferencing, and videoconferencing.

NCI Typical Study Process Flow



Volunteer Recruitment and Special Populations

NCI's Laboratory recruits volunteers from several sources including clinics, hospitals, health centers and major governmental agencies. Our aim is to provide access to a broad volunteer population that meets specific study criteria with the quickest turnaround possible for volunteer recruitment.

Screening

NCI's Laboratory places great emphasis on the importance of screening volunteers to define a suitable, healthy group of individuals. One of the key challenges in clinical research is the efficient recruitment of suitable volunteers to meet study design requirements. NCI has developed a network of resources and efficient procedures to meet this challenge effectively.

The stages of the screening procedure include:

Application Form - The prospective volunteer provides demographic details, medical and medication history.

Screening at the Clinical Unit - Medical and social history, physical examination, clinical pathology, urinalysis as well as urine drug screen virology blood testing where applicable. Vital signs also recorded at this time. In addition to these standard procedures, we are also able to meet study specific requirements for example, lung function tests, EEG recording, chest X-ray and psychometric testing among others.

Contact with Family Doctor (GP) - Medical history, drug therapy, allergies and advice regarding suitability for participation. Once volunteers have successfully completed the screening process they will be invited to become a study volunteer. They may also be invited to participate in future studies after an appropriate interval has elapsed.

Compliance Monitoring and Management - Among the biggest challenges in clinical research testing is ensuring compliance of the volunteers with study requirements. Hence NCI places great emphasis on volunteer communication, to encourage, verify and report compliance. NCI takes a hands on approach communicating with volunteers frequently and thoroughly.

Quality Assurance

Quality Assurance inspections are carried out during the conduct of the studies. The conduct of these inspections and audits is carried out according to Standard Operating Procedures (SOPs) by NCI's Quality Assurance personnel, who are independent of those responsible for the clinical study. Records of these inspections and audits are documented and distributed to study management for review. For all studies the draft and final reports produced by NCI are audited.

Quality Assurance inspections are carried out on critical phases during the execution of the study. Further inspections of routine, repetitive processes are also performed, although not necessarily on all studies.

Independent Ethics Committee

Each NCI clinical study is reviewed by an Independent Institutional Review Board.

An institutional review board (IRB), also known as an independent ethics committee or ethical review board, is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. The IRB conducts risk-benefit analyses in an attempt to determine whether or not research should be done.

IRB committees are composed of least five members consisting of experienced, diverse, experts and community volunteers of both sexes including scientists and non scientists.

IRBs are maintained by independent commercial entities as well as hospitals, health centers, and university institutions. NCI works with IRBs from these various institutions according to study needs.

Ethics Review dates are available upon request.