



## Clinical Trial Architect

« To optimize the launch of your Medicines or Healthy Food with successful Clinical Trials »

*A strategic partner for pharmaceutical, biotechnology and agrofood industries helping to design and coordinate clinical trials*

### A DOUBLE EXPERTISE:

- Scientific and clinical expertise for the design and the support to your trials,
- Operational expertise for the management of your studies (from the conception of the protocol to the clinical report) through a wide qualified investigator network and a strict compliance with regulatory and quality procedures.

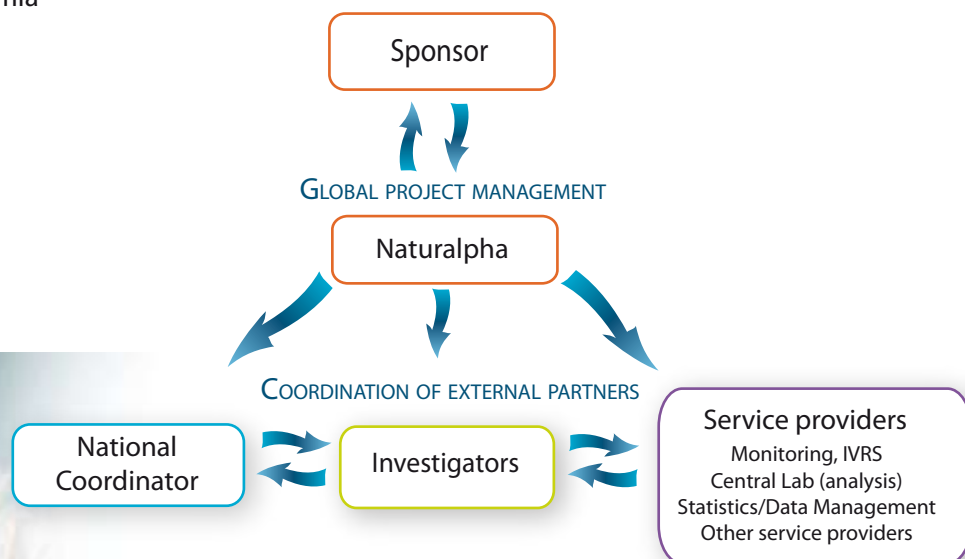
### AREAS OF EXPERTISE:

- Cardiovascular and metabolic diseases
- Atherosclerosis
- Obesity, weight management, satiety
- Diabetes, metabolic syndrome, dyslipidemia
- Respiratory diseases
- Inflammation disorders
- Joint health
- Gut health
- Skin health
- Mental health

### OPTIMIZATION OF YOUR CLINICAL DEVELOPMENT PERFORMANCE WITH:

- Clinical trials designed to fit your goals in close cooperation with international renowned experts, specialists in cardio-metabolic disorders and nutrition,
- Country specific set-up,
- Specialized partners rapidly mobilized to address your budget and planning specifications,
- Selected service providers complying with strict quality assurance procedures and audits.

### NATURALPHA - A SINGLE CONTACT FOR THE MANAGEMENT OF SPONSOR'S TRIALS



**NATURALPHA**

- Headquarters: Lille (France), office in Boston (USA)
- Founded in 2001, Turnover of 1.5 M€ in 2007
- Multidisciplinary team of 25 people

- Over 4500 patients recruited by Naturalpha
- Over 240 investigators sites in 17 countries participate actively in clinical trials coordinated by Naturalpha.



*Clinical trial conception and management from preclinical to clinical development phases, by a strong and targeted scientific and organizational support, with the same objective:*

**"More science, better recruitment and high quality management"**

## GLOBAL PROJECT MANAGEMENT BY NATURALPHA

### CONCEPTION OF STUDY DESIGN

- Scientific
- Regulatory
- Medical
- Operational

### COORDINATION

- Supervision & stimulation of recruitment
- Coordination of service provider activities
- Reporting to the Sponsor
- Budget & payment follow-up

### OPERATIONAL CONCEPTION

- Selection of participating countries & investigators
- Selection of qualified service providers
- Country-specific set-up
- Budget estimation & timelines

### QUALITY ASSURANCE

- Service provider assessment
- Project quality elaboration
- Site and service provider audits

### A dedicated team for your clinical study:

- Operational and transversal coordination by the Clinical Project Coordinator
- Clinical Project Leader
- Clinical Trial Assistants
- Quality and Regulatory Affairs Manager



## EXAMPLES OF OUR KNOW-HOW: Preclinical and clinical development plans, Feasibility studies, Phase I to Phase III studies, Clinical studies in Nutrition

### Pharmaceutical expertise:

- Many studies from Phase I to Phase III in the cardio-metabolic area (diabetes mellitus, hypertriglyceridemia, hyperlipidemia...) and in asthma
- Global accompaniment of companies along their compound development process (preclinical to Phase IIb clinical trials)

### Nutrition Expertise:

- Clinical validation of bifidogenic effect of a dietary fibre
- Clinical study on the effect of a functional food product on weight management
- Clinical study design for the determination of hypocholesterolemic effect of a functional food
- Clinical study design for the analysis of immunomodulation effect of a functional ingredient on children

### Thematic Studies Coordination / Scientific advisory boards

Thanks to Key Opinion Leaders and International Scientific Expert network, providing expertise in preclinical and clinical development, NATURALPHA arranges the set-up and animation of scientific advisory boards and coordinate all actions related to specific Task Force initiatives (protocol validation, valuation of clinical results, scientific committees).

