

# CLINICAL RESEARCH

*The ultimate substantiation*

a&r is not only a consultancy but also a full-service Clinical Research Organization (CRO) with a focus on natural health products. We have more than 20 years of experience in the natural product industry and have conducted more than 300 clinical trials with low active substances. We provide support in the development of highly customized study designs covering a broad range of clinical trial types and indications.

Full alignment of scientific validity, regulatory requirements, and business needs is the basis for every study performed.

## OUR SERVICES INCLUDE

- **Defining the scope of the project**
  - Understand your needs
  - Identify key issues
  - Identify all experts required
  - Conduct feasibility research
- **Designing the study**
  - Evaluate and identify the right study population (e.g. subjects at risk)
  - Select parameters/biomarkers
  - Conduct literature research
  - Develop the study design in line with guidelines and regulatory requirements in a cross-functional approach by liaising with regulatory experts in-house
- **Setting up the project**
  - Find the optimal set-up to maximize the success rate
  - Identify optimal external partners to meet customer's needs (data management, biometrician, labs)
  - Most successful recruitment due to our own study site including a subject database and network of investigators committed to natural health products
- **Managing compliance and logistics**
  - Specific support measures to improve compliance (e.g. alerts)
  - Continuous project risk management to ensure high-quality data and that project delivers in time
  - Temperature- and humidity-controlled storage capacities, IP distribution
- **Maximizing impact**
  - External KOL network for expert review

## OUR AREAS OF EXPERTISE

### Investigational products

- Food products (e.g. supplements, novel foods, FSMP, probiotics, infant nutrition)
- Medical devices (substance-based)
- Medicinal products (e.g. herbal medicines, OTC)

### Gastro-intestinal disorders

- Constipation
- Reflux
- Irritable bowel syndrome (IBS)
- Diarrhea
- Dyspeptic syndrome

### CNS/mental disorders

- Depressive state
- Chronic stress
- Insomnia and unrest
- Physical and mental vitality
- Weather sensitivity
- Cognitive impairment
- Mood

### Metabolic disorders

- Overweight / obesity
- Reduction of appetite
- Weight maintenance
- Reduction of blood glucose levels / prediabetes / diabetes mellitus
- Reduction of cholesterol

### Muscle/skeletal system

- Muscle cramps
- Osteoarthritis
- Blunt trauma

### Immune system/infections

- Common cold
- Viral infections of the respiratory system
- Immune-modulation
- Hay fever
- Cough & Cold

### Dermatological disorders

- Herpes labialis
- Acne vulgaris
- Dry skin
- Alopecia (hair loss)
- Hyperhidrosis plantarum (foot perspiration)
- Xerostomia (dry mouth)

### Women's health

- Menopausal complaints
- Imbalance in sex hormone levels
- Iron deficiency
- UTI

### Cardiovascular disorders

- Hypertension
- Arteriosclerosis

## CONTACT US

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