



# Nutrition



## The Harrison Clinical Research Group

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- ▶ Barcelona, Spain
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- ▶ Milan and Rome, Italy
- ▶ Vienna, Austria
- ▶ Warsaw, Poland
- ▶ Moscow, Russia
- ▶ Kiev, Ukraine
- ▶ Princeton, USA

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## Harrison Clinical Research Clinic for Nutritional Medicine



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HARRISON  
CLINICAL RESEARCH –  
YOUR FULL-TRUST PARTNER  
IN NUTRITIONAL CLAIMS

**Harrison Clinical Research** is a health driven independent contract organisation (CRO), founded in 1987.

Harrison Clinical Research offers the full range of services required for the successful development and registration of nutritional claims, new products from single studies to complete development programmes. Clinical studies can be carried out in our own clinics, while Market studies can be carried out either locally in any EU country, Russia, Israel or USA, or globally, as required.

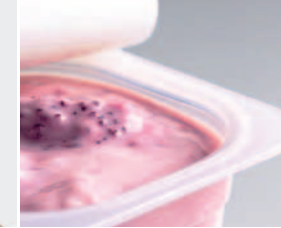
The head office of Harrison Clinical Research is located in Munich, Germany, where our Clinic for Nutritional Medicine, Data Management and Statistics, Medical Writing and Quality Assurance departments are based.

There are Harrison affiliates in ten European countries, Israel and USA.

All the activities of a Harrison Clinical Research office are performed in strict compliance with the relevant ICH-GCP guidelines. Harrison Clinical Research has been ISO 9001 certified since 1998. These comprehensive, quality services are performed to the highest international standards.

**Why a new Clinic for Nutritional Science?**

On 1st July 2007, the Health Claim Regulation (EU Regulation EC 1924/2006) came into force requiring clinical studies from the nutritional industry regarding functional/novel foods, food supplements and foods for particular nutritional purposes to claim specific health benefits.



**The Harrison Clinic for Nutritional Medicine**

This Clinic can conduct studies with healthy volunteers and in special volunteer and patient populations.

In addition to this full clinical service, the Clinic also offers Data Management & Statistical Services, Medical Writing, Quality Assurance and assistance with the necessary Regulatory work and submissions.

The Harrison Clinic for Nutritional Medicine has already gained considerable experience of nutraceutical and food studies, which often involve very large populations and complex study product supply and logistics.

**Volunteer database**

About 17,000 names – approx. 8,000 healthy, approx. 7,000 with specific diseases like hyperlipidemia, hypertension, skin disease, diabetes mellitus type II, gastrointestinal diseases, infection, osteoarthritis, ... and many, many more.

**Facilities available**

The Clinic for Nutritional Medicine has an independent clinical unit with reception and waiting room and examination rooms. There is also a laboratory for sample taking and preparation, rooms for medical treatment and storage facilities for study products and/or medicines. Additional clinical research facilities are available, if required, at our Clinical Pharmacology Unit, which has a clinic with a total of 36 beds. The clinic can handle even the most complex study designs up to studies with more than 1,000 subjects.

Harrison Clinical Research has established a close relationship with legal experts, who can support our clients inter alia with the clarification of the necessity of a clinical trial and the eventual submission of claims to the relevant authorities.

**Procedural flow**

- ▶ Development strategy for nutritional claims
- ▶ Clarification of necessity of a clinical study for a claim
- ▶ Study design
- ▶ Submission to ethics committee
- ▶ Execution of study, management and monitoring
- ▶ Data Management & Statistics
- ▶ Report Writing
- ▶ Quality Management and Consultancy
- ▶ Auditing
- ▶ Training
- ▶ Submission of Claim

