



Services Provided by Harrison Clinical Research Central Europe



We provide a complete clinical development service. Whether you require immediate assistance with a small task or professional advice and help with an entire project, our commitment to quality and customer service is guaranteed. We recognize the importance of effective communication in the achievement of your objectives. Our internal procedures and management structure ensure a flexible and responsive approach to your project. Our office in Vienna is an integral part of the Harrison Clinical Research Group, working to global SOPs and collaborating in full harmony on worldwide projects and to ISO 9001 standards. The close collaboration of our Vienna office with rigorously selected local CROs in Central Europe ensures quality results.

Sites Selection and Management

We provide GCP-experienced trial centers with access to a large patient population, negotiate site/investigator contracts, organize local patient insurance, administer study fees (in local currencies, when necessary), support clients in the rapid

turnaround of data queries and solve current study questions with sites.

Regulatory/EC Affairs

We provide study submission (with all necessary translations into local languages) and assist in timely receipt of study approval.

Project Management

Each project is individually managed to facilitate effective and timely achievement of study objectives and to ensure comprehensive client communication. All Project Managers have a medical background.

Monitoring, Phase I-IV

Studies are thoroughly monitored strictly in compliance with ICH/GCP requirements and local regulations, whether local or as part of international projects. Our CRAs participate in an ongoing training program, to ensure optimal data quality and compliance with SOPs, and have experience in a wide variety of therapeutic areas.

Investigator Meetings

We organize joint investigator and training meetings at your preferred location. General GCP courses or project/indication specific training courses are provided at investigational sites.

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Other Harrison Clinical Research Group Offices

- ▶ Ely, United Kingdom
- ▶ Brussels, Belgium
- ▶ Rehovot, Israel
- ▶ Barcelona, Spain
- ▶ Levallois-Perret, France
- ▶ Milan and Rome, Italy
- ▶ Warsaw, Poland
- ▶ Moscow, Russia
- ▶ Kiev, Ukraine
- ▶ Princeton, USA

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Harrison Clinical Research Central Europe

HCR Offices



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HARRISON CLINICAL RESEARCH – YOUR FULL-TRUST CRO

Harrison Clinical Research is an independent contract research organization (CRO), founded in 1987 in Germany with offices now in more than 14 countries.

Over the last 20 years Harrison Clinical Research has conducted more than 1500 studies covering all major therapeutic areas and all groups of products, from classical new drugs to biologicals, recombinant proteins and monoclonal antibodies.

Today Harrison Clinical Research is a rapidly developing company offering the full range of services required for the successful clinical development and registration of new pharmaceutical products and medical devices, from single studies to complete development programs. Clinical trials from Phase I–IIa can be carried out in our own clinics, while Phase II–IV studies can be carried out either locally or globally, as required, in different clinics throughout Western Europe, Israel and the countries of Central and Eastern Europe. These comprehensive, quality services, meeting sponsor's specific needs in clinical trials, are performed to the highest international standards, within time frames and budget.

In 1998, Harrison Clinical Research was awarded the ISO 9001 certification for quality management in clinical research.

Our head corporate office is located in Munich, Germany, where we have one of our two Phase I clinics and our centralized Data Management and Statistics, Medical Writing, Biotechnology and Quality Management departments.

We also have offices in the UK (Ely), Belgium (Brussels), Israel (Rehovot near Tel Aviv), Spain (Barcelona), Italy (Rome and Milan), France (Paris), Russia (Moscow), Ukraine (Kiev), Poland (Warsaw) and Princeton (USA). Our specialized Training department is located in Brussels, and our second Phase I clinic is in Rehovot. Our coordinating office for the Central European countries (including Austria, Czech Republic, Slovakia, Hungary, Romania, Bulgaria, Croatia and Slovenia) is located in Vienna.



Harrison Clinical Research in Central Europe

In 2004, Harrison Clinical Research opened its coordinating office for Central Europe in Vienna, Austria. Using this office as a base, Harrison employees provide the full range of clinical research services for studies performed in Austria, the Czech Republic and Slovakia. These services include monitoring, project management, site management and trial authorization.

For studies to be conducted in other Central European countries besides Austria, the Czech Republic and Slovakia, e.g. Hungary, Romania, Bulgaria, Croatia and Slovenia, among others, Harrison Clinical Research works together with a carefully selected partner CROs. Each of these CROs must first be approved through the HCR Qualification Program. A thorough selection process and continuous, close supervision by our office, before and during the trial, ensures the level of quality. In the past a number of these partners have become truly own affiliates integrated in our group.



Advantages of Central European Countries

- ▶ Highly qualified and well-motivated investigators
- ▶ Qualified healthcare professionals (mainly licensed physicians) engaged in clinical trials and working at contract research organizations
- ▶ High quality of clinical data
- ▶ Regulatory affairs in compliance with international standards
- ▶ Centralized medical services
- ▶ Availability of a broad network of large specialized clinics and hospitals to ensure fast recruitment of patients even with rare diseases
- ▶ Patients treated with the most modern methods/medications and treatment-naïve patients
- ▶ Many patients with high level of general education
- ▶ Various climate regions, similar to Western Europe

Study Sites and Investigators in Central European Countries

Wherever possible, we choose large reliable hospitals with broad experience in clinical trials according to ICH/GCP. Most of these hospitals are located in big cities, which means, easily reachable and access to a large patient population, e.g. Vienna, Prague, Bucharest, and Sofia.

In the Central European countries there is a high number of qualified and experienced physicians who are fluent in the local languages as well as English, and also computer literate. They are trained in ICH/GCP and many hold an international degree or have worked abroad.

Many of the sites are FDA/EMEA audited. On average, the Eastern European region is best with regards to observations compared to Western Europe and USA (ref. FDA). Regular inspections are conducted by the local MoHs.

