

Services of Harrison Clinical Research Representations in Poland, Russia and Ukraine



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. Representations in Poland, Russia and Ukraine are 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.

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. We effectively manage study logistics, including the reputedly challenging import, storage and timely distribution of study medication and export of biological specimens.

Regulatory/EC Affairs

We provide study submission (with all necessary translations

into local languages) and assist in timely receipt of study approval, including the receipt of study medication import licenses and study samples export licenses in Russia and Ukraine.

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.

Phase I

We conduct bioequivalence and pharmacokinetic studies in a broad spectrum of patient populations in specialized local Phase I and Phase IIa units.

Monitoring, Phase II-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.

Data Management

Data entry, international or proprietary coding are performed in accordance with SAS/SPSS procedures and ICH guidelines.

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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
- ▶ Vienna, Austria
- ▶ Princeton, USA

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Offices

Harrison Clinical Research

Poland
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CLINICAL RESEARCH - THE EUROPEAN WAY

Harrison Clinical Research is an independent contract research organization (CRO), founded in 1987 in Germany.

Over the last 20 years Harrison Clinical Research has conducted more than 1400 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 stable, 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 Europe, Israel and the countries of Eastern Europe. These comprehensive, quality services, meeting sponsor's specific needs in clinical trials, are performed to the highest international standards, within timeframes and budget.

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

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

We also have offices in Ely (UK), Brussels (Belgium) where our training department is located, Rehovot near Tel Aviv (Israel) where our second Phase I clinic is located, Barcelona (Spain), Rome and Milan (Italy), Paris (France), Vienna (Austria) and Princeton (USA).



Harrison Clinical Research in Countries of Central and Eastern Europe

Harrison Clinical Research has a long tradition of working in the countries of Central and Eastern Europe (CEE).

In 2007 Harrison Clinical Research opened new representations in Warsaw (Poland), Moscow (Russia), and Kiev (Ukraine).

This expansion was a result of the large number of North American, Western European and Asian clients and their increasing demand for state of the art, medically driven clinical research with high recruitment rates and total data integrity.

To cope with the sustained growth of its clinical operations in the three largest countries of the CEE region, Harrison Clinical Research has recruited three strong teams of clinical development professionals who have, between them, an impressive number of years of clinical trial experience in the biopharmaceutical and CRO industries and excellent medical and scientific credentials.

The local teams have a long track record of achievement in sophisticated studies and the proven knowledge, experience and skills to control all parts of the clinical research project. They can contribute "local know-how" of the regulatory environment in their countries combined with

Harrison's values of integrity, reliability and client orientation. In addition, a large team of well trained CRAs can be mobilized for large Phase III and Phase IV trials, backed up by strong data collection and electronic data capture capabilities.

Advantages of CEE Countries

- ▶ Large patient population, concentrated in big cities, enabling fast patient recruitment
- ▶ 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, multinational population with a prevalence of Caucasians
- ▶ Various climate regions, mainly similar to European
- ▶ 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
- ▶ Significant cost saving
- ▶ Less regulatory burdens, regulatory affairs in compliance with international standards

Study Sites and Investigators in CEE 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 large cities, which means, easily reachable and access to a large patient population, e.g. Moscow (15 Mio.), St. Petersburg (5 Mio.), Kiev (2.8 Mio.), Warsaw (1.8 Mio.). In Russia and Ukraine the institutions are chosen from a list of MoH approved sites, which shortens the approval time.

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

Site personnel are trained and experienced in completing eCRFs and using IVRS. Sites are equipped with personal computers and broadband internet access.

Many of the sites are FDA/EMA 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 local MoHs.

Ethics and Regulatory Processes in CEE Countries

All international trials are reviewed by central/local Independent Ethics Committees which act and are constituted according to ICH/GCP. The regulatory process is transparent and similar to that in the rest of Europe.

The average Regulatory Authorities and Ethics approval time for trials is about 8 weeks. Receiving permissions for the import of medicinal products and export of biological specimens (in Russia and Ukraine) usually takes an additional 2 weeks. Harrison Clinical Research employees have the expertise to move the process forward as quickly as possible.

