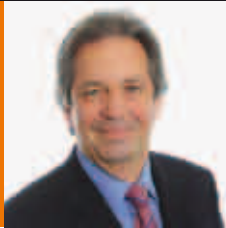


**Harrison  
Clinical  
Research**



**Harrison**



- ▶ **Development Strategy**
- ▶ **Regulatory and Scientific Advice**
- ▶ **Clinical Pharmacology Unit**
- ▶ **International Project Management and Monitoring Services (Phase I–IV)**
- ▶ **Quality Management Services**
- ▶ **Auditing Services**
- ▶ **Data Management**
- ▶ **Biometrics**
- ▶ **Medical Writing and Translating**
- ▶ **Training**

# HARRISON



Munich, Germany

Brussels, Belgium

Princeton, NJ, USA

## Outsourcing Dedication

**Harrison Clinical Research operates globally while maintaining the closest link to you. Flat hierarchies and smooth processes enable us to operate efficiently and quickly.**

Harrison Clinical Research (HCR) is an international CRO with offices throughout Europe, Israel and the USA offering you a full service solution for your clinical research projects, both globally and locally. Our experienced staff provide a strong dedicated team for your projects in the clinical research area as a completely outsourced project or as individual tasks alone.



**Flexibility and understanding** of client needs is part of our personality as a company.

Our head office was founded in 1987 in Munich, Germany, where our Pharmacology Unit is located as well. Over the last years we have expanded internationally with a group of affiliates in the UK, Belgium, France, Italy, Spain, Austria, Israel, Russia, Ukraine, Poland and the USA.

The activities of HCR range from phase I and II–IV studies in Europe and worldwide. The local know-how of our affiliates guarantees that your trials will be conducted in accordance with all international and local regulatory regulations.

We offer the full range of services required for the successful clinical development and registration of new pharmaceutical and biologic products, medical devices and nutraceuticals, from single studies to complete development programs. Over the last years we have conducted studies covering all major therapeutic areas and all classes of products.



### **Phase I Services**

HCR has its own Clinical Pharmacology Unit located in Munich (Germany). Our unit performs state-of-the-art studies ranging from first-in-human to tolerability, including interaction, PK/PD and bioequivalence trials.

Our unit has broad experience with all types of administration routes and galenic formulations and offers validated pharmacodynamic methods for cardiovascular, CNS, metabolic and other areas. All studies conducted in our Clinical Pharmacology Unit are performed within an adequate environment assuring telemetry and the maximum safety of our volunteers. Experienced medical evaluation with our own medical team is available.

### **Phase IIa Services**

Our Clinical Pharmacology Unit has access to the following special patient populations: elderly, pre- and post-menopausal women, obese subjects, smokers/non-smokers, subjects with chronic kidney or liver dysfunction as well as patients with various chronic diseases: diabetes mellitus, chronic obstructive pulmonary disease, asthma, hypertension, hyperlipidemia, psoriasis, fibromyalgia, osteoarthritis, rheumatoid arthritis, common infectious diseases, back pain, osteoporosis, endocrine dysfunction, HIV and others.

Our databases are updated regularly, allowing immediate access to patients on demand. Established contacts to medical specialists, patient organizations and public routes in all medical fields allow fast recruitment in many indications.

### **Long-term out-patient Studies**

We have a separate clinical unit dedicated to outpatient-only studies, such as nutritional medicine or vaccination, where high numbers (1000+) of volunteers can be recruited in a very short period of time with follow-up, observation or treatment over years.



## **Project Management and Global Monitoring Services: Phase I, II, III, IV**

We tailor our services individually to the needs of our clients and the unique study requirements of each product. HCR has gained extensive experience that enables us to minimize delays and surprises during the conduct of trials by thoroughly planning and dedication.

We have experience in the management of clinical trials in phase I, II, III and IV in nearly all medical fields, with a special focus on Cardiovascular, CNS/Neurology/Psychiatry, Dermatology, Diabetes, Immunology, Vaccination, Infectious Diseases, Oncology, Ophthalmology and Nutraceuticals.

We offer a wide network of experienced monitors all over Europe, Israel and the USA. Today's requirements for global development programs are served by our alliance with our CRO partners. We can thus offer you direct access to research activities in the world's key markets with the continuous high standard of quality and GCP.

Harrison Clinical Research operates according to a specific project management system. We allocate the project manager most appropriate for your project (according to the type of project, location, indication, etc.) who will be your key contact within Harrison Clinical Research for the duration of the study. You can be sure that you are working together with highly efficient, experienced, dedicated, well trained and medically oriented people.

HCR is ISO 9001:2001 certified for quality management, and our creed is good communication and the best possible support for you. By utilizing successful regulatory strategies we can take the best path forward to approval. We smoothly integrate other members of our group into our processes and prepare all study reports, such as clinical study reports and safety reports according to our high quality standard.

**We know that project management is more than meeting timelines and coordinating people but truly making the sponsor's needs ours.**



### **Data Management and Biometrics**

Our data management and biometrics facilities are centralized in our headquarters in Munich (Germany) and Princeton (USA). All of our services are performed according to ICH standards: paper and e-CRF design, database preparation, double data entry, verification, data query handling, medical coding (using dictionaries including MedDRA and WHO-DD, as required), preparation of CDISC SDTM compliant data, randomization and statistical analysis (using SAS®). Our biometrics department provides consulting and design advice which is especially important at the early stage of the project planning. This includes protocol review and design considerations, sample size estimation, statistical analysis plans and state-of-the-art statistical analysis.

### **Regulatory and Scientific Advice**

Diligent study planning facilitates smooth and speedy approval procedures by IRBs/ECs and regulatory authorities. Our regulatory services group offers support in your study start-up activities, can act as your applicant to Ethics Committees and Competent Authorities according to international and national guidelines and ensures the regulatory compliance (e.g. submission of amendments, serious adverse event reporting throughout the course of the study).

We perform clinical studies according to the highest medical standards to ensure the best approach to obtaining marketing approval. Our advisory regulatory service provides you with the full range of regulatory services covering all stages of drug development.

### **Medical Writing and Translating**

The medical writing department of Harrison Clinical Research consists of English and other native speakers, all of whom are highly qualified in either medicine or life sciences with many years of experience in medical writing.

This department prepares all study documents including clinical study protocols, investigator's brochures, patient information/informed consent, clinical study reports, and scientific articles. Study protocols and reports are created in ICH E3 format or can be written according to sponsor's SOPs and templates. Our medical writers work in close cooperation with our statistical and medical teams. We also provide assistance in the authoring of IMPDs and the writing of clinical reports in the eCTD format. We provide you with the best possible service, high-quality documents and rapid turnaround times.

Many years of experience in the translation of all study documents – notifications to authorities, protocols or synopses, patient information leaflets and medical reports – make us a reliable and valuable partner for your translations.

Member of





## Quality Assurance

Our QM team involved in trial specific QA activities is fully independent from operational tasks and therefore meets all requirements specified in, for example, standards like ENGAGE or ISO 19011.

The internal quality system at Harrison Clinical Research is an ongoing program to ensure that all studies are ICH/GCP and GMP compliant and follow applicable Standard Operating Procedures (SOPs), or Quality System Procedures (QSPs). The Quality Management Department issues a Quality Management Plan for each new study.

The Quality Management Plan outlines the quality procedures that have to be implemented during the clinical study. It includes regular scheduled audits and spot checks for the study. The audits cover all functional areas including critical suppliers, project management, clinical monitoring, regulatory affairs, safety, investigator and trial master files, data management, project deliverables (including study reports, tables and listings) and case report forms.

## GXP Engaged Auditing Services

After implementation of the Directive 2001/20/EC, and as specified in article 16 of Commission Directive 2005/28/EC, Quality Control and Quality Assurance are a legal requirement for Sponsors. Our Auditing team has gained vast experience, conducting well over 500 audits since 1998. Sponsors sub-contract to the independent group audits, which follow the applicable standards of ISO 19011, and the ENGAGE Optional Guideline for GCP Compliance and Quality Systems Auditing, from the European Network of GCP Auditors and other GCP experts. Audits are conducted according to the auditing plan, which is formally released upon mutual agreement with the sponsor. Audit reports are written within defined time frames, peer-reviewed as all other documents generated from the GXP Engaged auditors, released and distributed. A formal signed documentation, confirming that all findings have been addressed, is always considered a part of the audit.

## Training

The European Centre for Clinical Research Training (ECCRT) is a company of Harrison Clinical Research located in Brussels and its primary focus is to serve as a training centre for professionals in the pharmaceutical, biotechnological and academic clinical research GCP environment.

The courses offered are tailored to every level of experience and are divided into modules ranging from an introduction to clinical research and monitoring to current regulatory requirements of clinical trials and specific medical research areas. A number of courses on elements of successful project management, clinical risk management and soft skills such as communication for managers and the clinical research team are also provided. Tailored courses, specifically designed to the client's training requests and given on-site at the client's company are also provided.

All courses are currently given in Brussels and, through collaboration with a leading educational provider. The most popular courses of ECCRT are also available in Italy, Germany and Austria.

Please visit us at [www.eccrt.com](http://www.eccrt.com).

All training queries can be addressed to [eccrt@harrison.be](mailto:eccrt@harrison.be).

# Harrison

## Harrison Clinical Research Group

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