





## mission statement



Our goal is to co-operate actively in the ethical, scientific research programs of multinational CROs, pharmaceutical and biotech companies through organizing and managing clinical operations in Central and Eastern Europe by serving our client.

To achieve the highest quality service, we concentrate youthful, leading clinical research professionals who are able to work with full commitment for the success of the research project.

While we expand our client's activity into the Central and Eastern European region, we also open a gate to a region where the patient recruitment potential is excellent. GCP is fully implemented and qualified clinical investigators are both co-operating in and interested in their involvement in research projects.

## company history

HungaroTrial Ltd. was founded by Dr. Lajos Sárosi in 1999 as a local CRO in Hungary. Dr. Sárosi gained his clinical research experience in the USA and in the clinical operational team of Zeneca and Quintiles.

As the result of the success and high quality work, HungaroTrial has rapidly become appreciated and valued in Hungary. Soon, HungaroTrial expanded their activities to the leading research countries of Central and Eastern Europe. The management of HungaroTrial is fully committed to continuing the organic development of the company in the Central Eastern European region, while creating CRO networks with partners from other regions is also an attractive development option.





## services



HungaroTrial Ltd. offers the following services for placement of Phase I.-IV. clinical trials in the Central and Eastern European region:

### Feasibility Analysis

We proactively assist every clinical aspect of the trial and evaluate the feasibility based on our previous experience, hospital databases and interviews with clinical experts.

### Site Selection

Site selection procedures and criteria are well defined by the HT SOP, which guarantees the involvement of sites with the best patient recruitment potential and ensures good GCP compliance.

### Regulatory and EC Affairs Management

The regulation of clinical trials in the Central and Eastern European countries is being co-ordinated through EU directives. Regulatory acts are often changing, therefore local expertise is essential.

### Hospital and Investigator Grant Negotiation

Although investigator fees in Central Eastern Europe are significantly lower than those in the Western Europe or in the US, investigators in the region are still motivated by the opportunity, because of the low earning potential in the health care sector. Finding the proper grants and negotiating the share split between the hospital and investigator can be a key success factor of the trial.

### Monitoring

HungaroTrial's well-trained CRA team is able to work under deadline pressure. Some of the CRAs have already achieved international (ACRP) qualification.

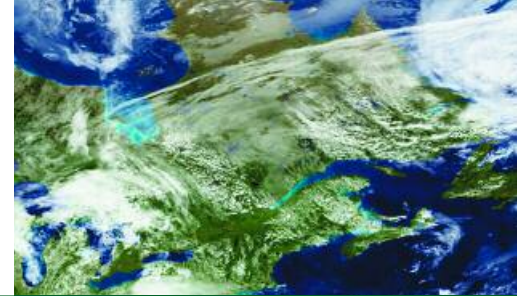
### Data Management and Statistics

We provide a variety of data capture alternatives enabling the quick data process, even in trials including the large number of patients. Trial data is analysed based on the protocol and/or the Statistical Analysis Plan.

### QA Site Audit

HungaroTrial is experienced in auditing the clinical trial's GCP and protocol compliance, as well as the compliance with the local regulatory requirements.





## Owner-driven company with a flat management structure

HungaroTrial is led by Dr. Lajos Sárosi, the owner of the company. There are no shareholders to dilute profit or dictate policy. Dr. Sárosi is actively involved in all aspects of the company's activities, including the clinical projects. He makes every effort to ensure that HungaroTrial provides clients with timely and efficient services, of the highest possible quality.

## Flexibility and responsiveness

HungaroTrial's flat management structure offers sponsors many benefits: Implementation of actions and corrective procedures is fast and flexible, therefore the company is able to respond quickly to new requests and necessary changes in directions in ongoing projects. This remarkable flexibility and responsiveness has been proven several times in previous projects.

## Low overhead and cost-effectiveness

HungaroTrial is a small company without the costly bureaucracy inevitable in larger organizations. The high proportion of clinical research professionals and low overhead costs allow HungaroTrial to pass the savings on to our clients, making our services not only high quality, but also highly cost-efficient.

## Highly personalized service

HungaroTrial's highly personalized service starts with the positive attitude of our employees. When sponsors or investigators call our office, they can always be sure that whoever picks up the phone will know who they are and which study they are involved in, whether or not that person is dealing directly with that study at that time. HungaroTrial's low staff turnover ensures that the projects are more likely to be staffed by the same team from beginning to end. This provides consistency and continuity at both the investigational site and with the sponsor.

## On board experience

In Central and Eastern Europe, clinical research professionals are mostly medical doctors and pharmacists because of the significantly higher salaries in the pharmaceutical industry than in the healthcare sector. With careful selection from the highly educated CRA and project manager pool, HungaroTrial was able to build up a strong team and further educate each member maintain it through continuous training. Key research members of the staff are full time, office-based employees. They are fully committed to the company and able to work under demanding pressure to retain total client project loyalty.

## Selected Clinical Trial Experience

Disease Area	Indications	Sites
Oncology	Breast Cancer (FISH+)	14
	Breast Cancer adjuvant therapy	6
	Breast Cancer	2
	Non Small Cell Lung Cancer	3
	Prostate Cancer	16
Cardiovascular	Acute Myocardial Infarction	9
	Deep Vein Thrombosis	19
	Peripheral Arterial Occlusion	7
Rheumatology	Rheumatoid Arthritis	3
	Osteoarthritis	3
	Low Back Pain	10
	Osteoporosis	4
CNS	Schizophrenia	27
	Generalized Anxiety Disorder	6
Urology	Kidney Stone	6
	Incontinence	17
Anti-Infective	Nosocomial Sepsis	30
	Viral Flu	15
Paediatric Metabolic Disease	Nutrition	1
	Diabetes	12