COMPANY
INTRODUCTION

HungaroTrial
Contract Research Organization

hungarotrial.com

HungaroTrial

The Best CRO Partner in Central & Eastern Europe

CEO 인사말

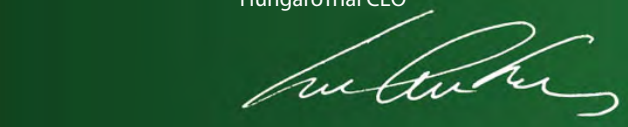
HungaroTrial은 헝가리에서 가장 긴 역사를 지닌 CRO로, 1999년 설립 이후 중동부 유럽 전체로 지사를 늘려가며 빠르게 성장해 오고 있습니다. 전 세계의 고객사와 함께 다양한 프로젝트를 10여 개 국에서 진행해오고 있으며, 이 지역에서 선도적 위치에 있음을 자부합니다.

저는 눈부신 발전이 이루어지고 있는 한국의 의료기기와 바이오 및 제약 산업에 큰 관심을 기울여 왔으며, 증가하는 글로벌 임상시험 추세에 맞춰 함께 발전 방향을 모색하고자 합니다.

지난 20년이 넘는 기간 동안 저희가 쌓아온 경험과 전문성, 그리고 신뢰관계를 바탕으로 최상의 서비스를 제공함으로써 한국의 글로벌 임상시험 및 신약 개발의 성공을 지원하겠습니다.

HungaroTrial이 귀사의 성공 동반자가 될 수 있기를 진심으로 바랍니다.

의학박사 러요시 샤로시 (Lajos Sárosi, MD)
HungaroTrial CEO



Our experience working with Korean Sponsors

HungaroTrial is a market leading regional CRO based in Central and Eastern Europe (CEE). Since 1999, we have helped healthcare organizations around the world – including pharmaceutical, biotechnology, and medical device companies – drive effective clinical development. In addition to our Sponsors in the United States and Western Europe, HungaroTrial has partnered with several Korean Sponsors, as well.

Since our first project on behalf of a Korean pharmaceutical company, we have been contracted by Korean Sponsors to manage several important initiatives, including the fast start-up of COVID-19 trials, an oncology trial, and a rare disease study in Central and Eastern Europe.

One of our Korean Sponsors, who is working with a global CRO, selected us to manage their trial in the CEE region. This honor was the result of a productive partnership to date, as well as HungaroTrial's understanding of Korean culture and expectations.

HungaroTrial provides its Korean clients full-service coverage. We are fully capable of reviewing IB and IMPD documentation and adapting these documents to EU standards.

Our Director of Business Development, who is a native Korean speaker, ensures clear communication and a high level of responsiveness to time sensitive requests.

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CRO Leadership in Central & Eastern Europe

International References

340+
clinical trials in CEE

20+
operating countries

12,000+
enrolled study patients

85
employees globally

158
audits / inspections

110
Clients and growing

Our Values

Experienced, Engaged Medical Staff

Our project leadership team includes 12 medical doctors with relevant scientific and clinical expertise. Crucially, our team is defined by low turnover, assuring stability throughout your project.
Our medical team is deeply involved in all core services, including study planning, protocol writing, site and investigator management, medical monitoring, adverse experience evaluation, and site staff training. 100% of our clinical staff has completed training in New EU Clinical Trial Regulation (EU 536/2014).

Superior Regional Presence

We have local offices and teams based in the CEE region, placing us close to the crucial work we execute for our clients.
Additionally, we have built working relationships with the best sites and investigators in the region, lending unparalleled quality and credibility to your clinical development program.

Rapid Start-Up and Strict Timelines

Our knowledge, skills, and relationships allow us to initiate clinical trials quickly and effectively, helping you meet critical timelines.
A vast majority of our clinical trials, including rescue trials, are up and running in 2-3 months. We proudly deliver 95% of projects on time, honouring the trust our clients place in us.

Patient Enrolment Confidence

We use proven patient enrolment tools to optimize enrolment and retention across your entire study. Our medical team will analyse your protocol design, local standards of care for targeted indications, site motivations, participation barriers, and competitor presence, allowing you to initiate projects with confidence.

Robust Quality Management

HungaroTrial invests heavily in a world-class quality management system for clinical trials, which represents a top imperative for our company. We perform regular, robust internal audits that support the continuous improvement of procedures and ensure the highest quality standards possible.
We received our ISO 9001:2015 Certificate in 2019.

Basic Facts in
Central & Eastern Europe

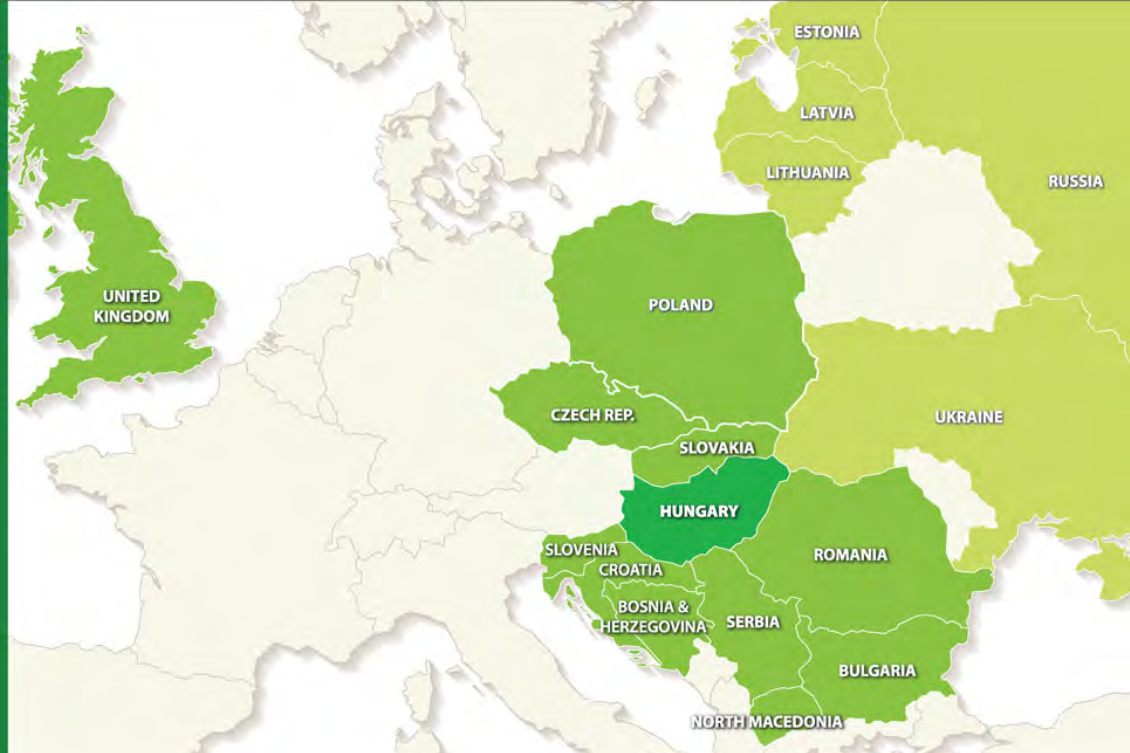
Centralized and well-organized health care system

Large central hospitals are geographically positioned to host larger patient populations

Modern medical technology is readily available (CT, MRI, etc.)

State-financed health care system (private health insurance isn't used widely)

Highly skilled medical staff following global standards and tradition of medical education



Our History

1999	HungaroTrial is founded by Dr. Lajos Sárosi as CRO operating in the CEE region
2002	Performs the first multi-country clinical trial
2005-2007	Opens offices in Romania, Slovakia and Serbia
2009	Expands reach to include Ukraine and Russia
2011	Begins operations in Poland and Bulgaria
2014	Begins operations in Bosnia
2015	Opens office in Bulgaria
2016	Establishes Client Relations Office in London, United Kindom
2017	Opens office in Czech Republic
2020	Begins operations in North Macedonia
2022	Opens offices in Bosnia, North Macedonia and Poland

HungaroTrial
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World-Class Clinical Trial Services

Scope of services

Set-up phase → **Active phase**

Protocol writing & ICF preparation

IMPD preparation

Feasibility study & Advice
- Identification of countries, sites and motivated investigators
- Recruitment potential
- Pre Study Visit (PSV)
- Regulatory strategy advice

Preparation
- Study documentation
- RA & EC submissions
- Team training
- Site visits
- Qualification of Sites & Vendors

Study management
- Monitoring
- Project management
- Medical Monitoring
- Coordination of all actions & Vendors
- Data management • Statistics • CSR writing • PV

SOPs | **On-going RA tracking** | **On-going staff training** | **Site & Vendor Audits** | **Internal Audits**

Quality Assurance

HungaroTrial is the Regional Expert in CEE

For over twenty years, HungaroTrial has been working in the region of Central and Eastern Europe through **local staff** based in dedicated **local offices**.

If you are searching for:

- the best trial sites for your study
- quality solutions for IP importation, storage and distribution
- a pathway through complex regulatory environments

… then we're ready to help.

Since its inception, HungaroTrial has maintained a robust clinical trial site database in CEE. Our local team has rich experience working with the region's premiere trial sites and Key Opinion Leaders, as well as third-party service providers such as laboratories, IP distributors, and home nursing services.
Every service provider is hand-picked by our leadership team and represents the region's most capable institutions.
We select only the best for you!

Meanwhile, our Regulatory Team closely monitors changes to clinical trial regulations and application procedures in each country comprising the region.
We collect and update our catalogue of relevant regulatory acts and provide routine training to our entire Clinical Staff.

IB, IMPD review and update to EU requirements

It might happen that the EU standards and expectations of the local Competent Authorities require a more detailed Investigator's Brochure (IB) and Investigational Medicinal Product Dossier (IMPD) than expected.

In these cases, we are more than ready to help you. Our experts will review your IB and IMPD, and update them where necessary for full regulatory compliance.

Protocol consultancy and writing - 12 MDs on board

The HungaroTrial Team brings together a diverse, dynamic, and valuable set of medical competencies. We have 12 MDs on board, many with over 10 years of clinical practice experience, including specializations in different therapeutic areas (such as cardiology, rheumatology, infectiology and more).

Our Medical Team can perform a professional review of your study protocol, offering suggestions to:

- ensure close compliance the regional standard of care
- optimize patient enrolment potential
- improve chances of fast-track approval

We work closely with internationally recognized Key Opinion Leaders in the CEE region, factoring their expertise as Medical Advisors in our study design.

Assistance in obtaining EU GMP Certificate – EU QP available

If your manufacturing facility can not provide an EU GMP certificate, we will assist in finding an EU QP, organize an on-site or remote audit, and secure the appropriate EU GMP Certificate available for your Clinical Trial Application process.

In Non-EU countries in the CEE region, QP declaration is not required, so time and cost can be saved.

Supporting EMA Scientific Advice Process:

- If you would like to get the EMA scientific advice to see if your development strategy is acceptable to EU standards, we can provide support for your application process.
- HungaroTrial has Small and Medium-size Enterprise (SME) accreditation at EMA, 90% of EMA SA cost reduction is available for you through us.

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HungaroTrial's Success Stories

COVID-19 medication study for a Korean Sponsor

HungaroTrial successfully managed a phase II./III. clinical trial for a Korean Sponsor researching a new COVID-19 medication. The trial was based in Serbia and Macedonia.

Upon initiation, HungaroTrial managed to enroll 103 patients in just 11 days, ensuring a timely completion of the study.

Additionally, HungaroTrial was able to:

- secure fast track approvals in both countries
- ensure a quick start-up, including fast contract signature
- select excellent sites with proven enrolment potential
- conduct fast data base cleaning for interim analyses (85% of the study data coming from our patients were generated in 28 days and cleaned in less than 1 month).

Phase II study in Pneumonia indication

A US-based biotech company reached out to HungaroTrial for a Pneumonia study. The patient enrollment began in the US, but the team encountered difficulties and turned to us for help.

To assist the Client, HungaroTrial selected case-appropriate as well as productive sites in the CEE region. Subsequently, we could enroll the required number of patients in a comparatively short time.

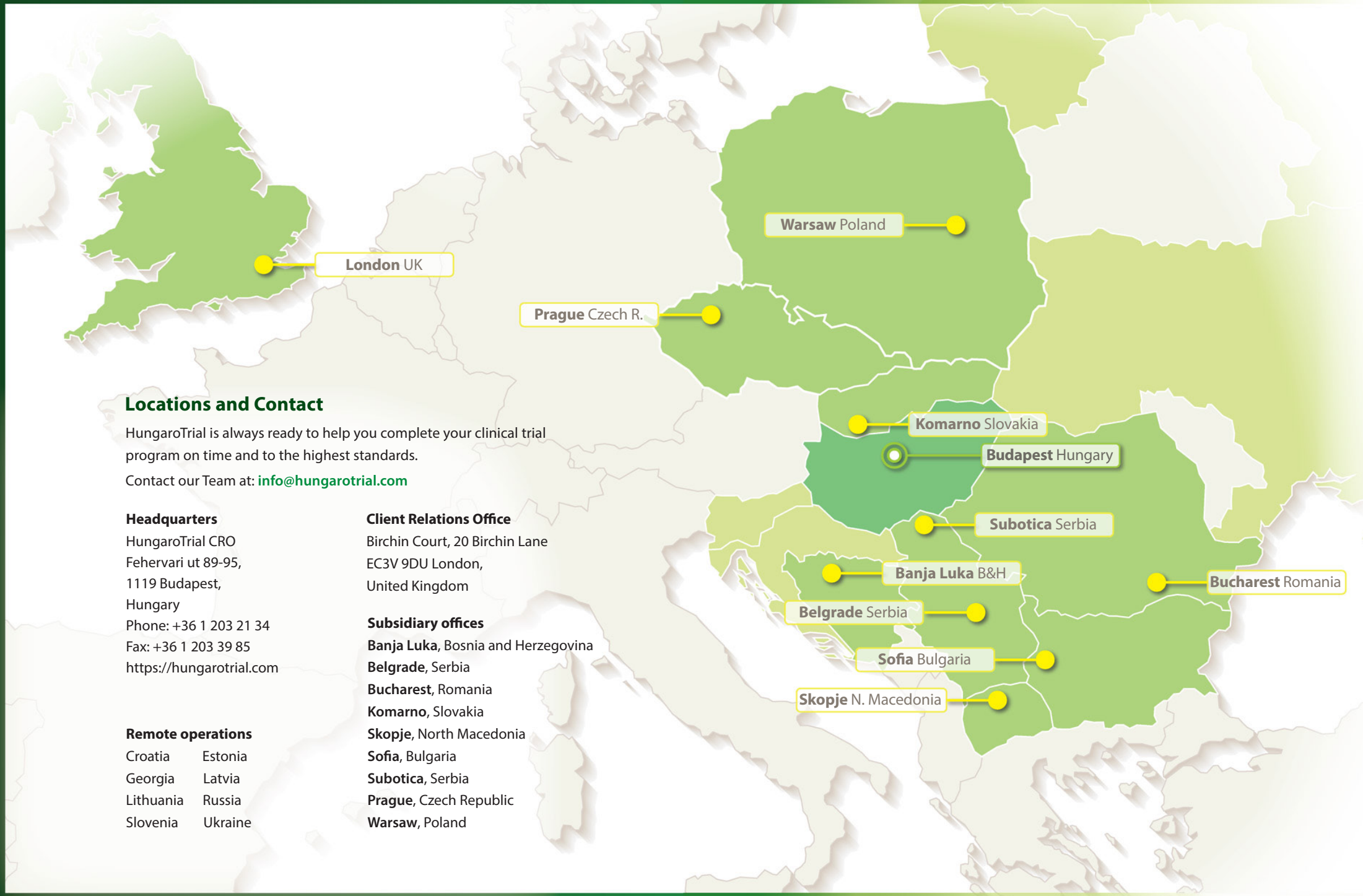
USA		CEE
0.03		**0.97**
13/13/29	**patients/month/site**	420/9/48

Phase III study in Hypoparathyroidism

HungaroTrial was contacted by an American biotech company to execute a rescue project. In the USA, the enrollment figures were far below the planned rate. As the indication was for a rare disease and the patient selection criteria were very limiting, it was extremely difficult to find suitable trial sites and subjects.

Rapidly HungaroTrial managed to set up the project in Hungary and enrolled 26 patients instead of the contracted 18 patients which was 144% improvement.

USA		HUNGARY
18 months	**duration**	**3** months
3.5 patients	**enrollment/month**	**8.6** patients
76% (84/110)	**achievement rate** (enrolled/planned)	**144**% (26/18)



Locations and Contact

HungaroTrial is always ready to help you complete your clinical trial program on time and to the highest standards.

Contact our Team at: **info@hungarotrial.com**

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United Kingdom

Subsidiary offices
Banja Luka, Bosnia and Herzegovina
Belgrade, Serbia
Bucharest, Romania
Komarno, Slovakia
Skopje, North Macedonia
Sofia, Bulgaria
Subotica, Serbia
Prague, Czech Republic
Warsaw, Poland

Remote operations

Croatia	Estonia
Georgia	Latvia
Lithuania	Russia
Slovenia	Ukraine

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