



# Clinical research in Hungary:

## Tested and Approved

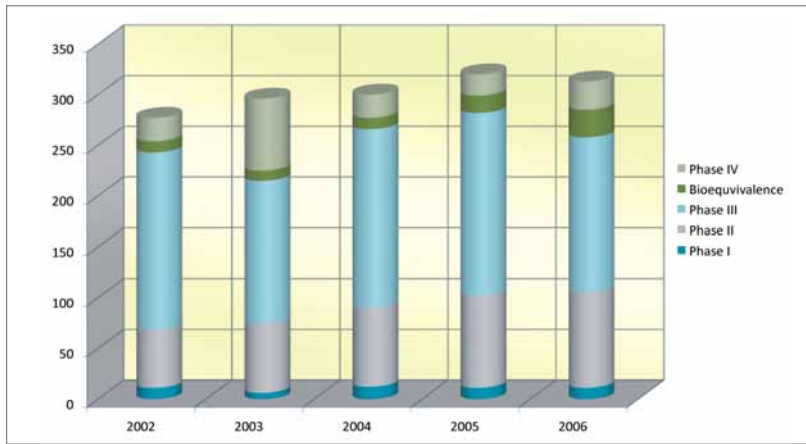
*Content prepared by: CONVINCIVE Consulting in 2009*

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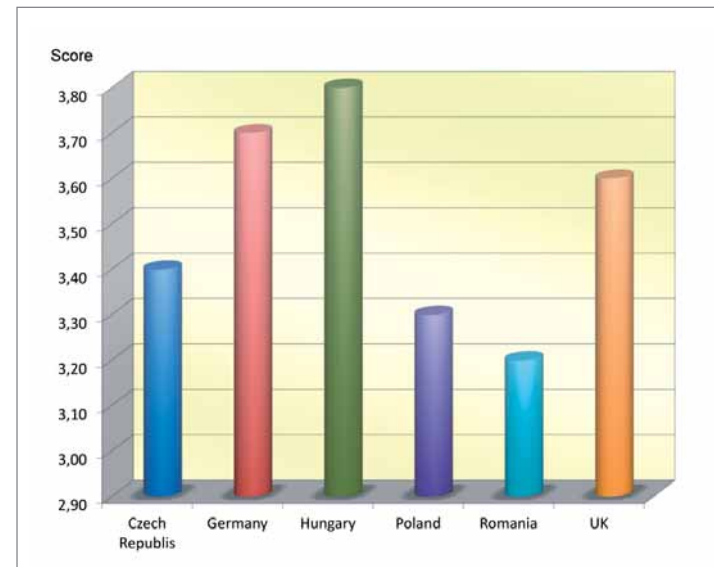
# Around 300 Clinical Trials are Performed in Hungary Annually –

an outstanding number considering Hungary's 10 million population. Hungary has multiple advantages as a venue for clinical trials.



## Buck Consulting International surveyed six countries according to the following criteria:

- Labour costs
- Patent population
- Labour availability
- Available infrastructure
- Regulatory framework
- Business climate
- Accessibility



Source: National Institute of Pharmacy, September 2009

Source: Buck Consultants International, 2009

# Why Outsource Your Clinical Trials to Hungarian-based CROs?

**Some cost advantages** still exist as compared with the West (not more than 10%-15% ) but there are several other good reasons why a large number of pharmaceutical and biotech companies come to Hungary and Central and Eastern Europe to conduct clinical trials.

**Fast and timely patient recruitment** is a natural advantage favouring CEE studies.

- There is a higher incidence of certain disorders, such as cardiovascular and pulmonary diseases, in CEE countries than in Western countries. These disorders may be more common due to environmental reasons or lack of public awareness and less access to preventive care.
- Patients are still not over-treated (drug-naïve) and are therefore not resistant to a wide array of medicines.
- Patients are motivated because clinical trials offer the opportunity to access expensive and innovative medication free of charge. Healthy volunteers in phase I studies appear to be more motivated by financial rewards.
- A major factor is investigator motivation. Financial rewards, opportunities for professional development and publications, and access to modern therapies and medical equipment are all major motivational factors for CEE physicians.
- The formerly centralized health systems of CEE countries have resulted in large medical centers with high numbers of patients who can be quickly enrolled in clinical trials.

- Internationally recognized infrastructure, modern hospitals and diagnostics equipment allow even the most complex trials.
- There is a high density of well equipped Phase I platforms.

**Outstanding data quality** and rapid patient enrollment are results of excellent patient and investigator compliance. The qualifications of local study monitors is above the international average, including for English language skills.

**Well defined legislation and regulatory processes conform to the latest EU Directives** to allow smooth study initiation and management, documentation, while decision-making processes are well defined, open and clear.

**Hungarian-based regional CROs** with offices in multiple countries are able to manage regional multi-country clinical trials.

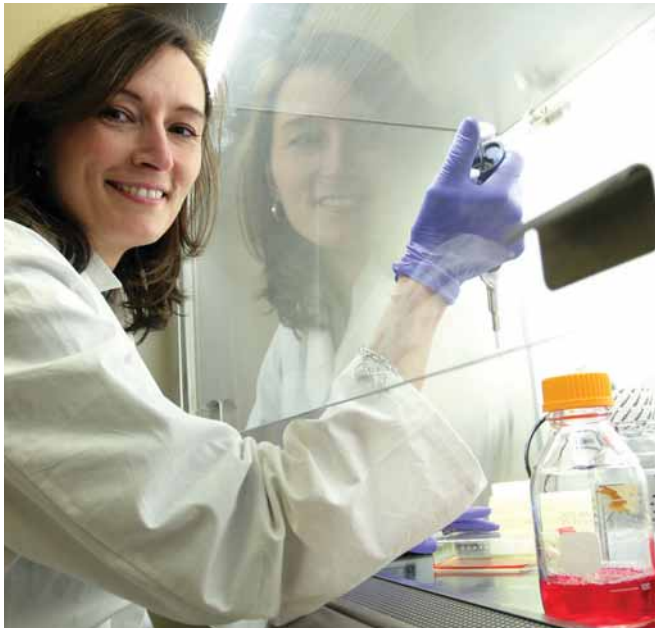
*“Hungarian investigators are genuine partners for us, rather than executors of protocols carved in stone. Indeed, they provide a valuable contribution as early as the study design phase, which is very much appreciated and extremely helpful.”*

– Zsuzsanna Bors, Clinical Research Director of AstraZeneca Hungary

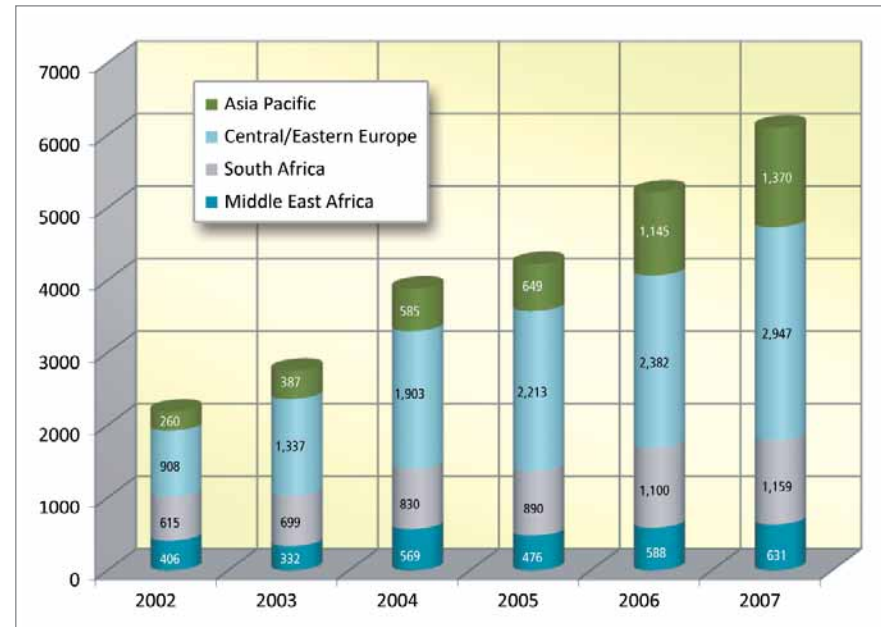
Source: *The CenterWatch Monthly*, 2008 August

# Central and Eastern Europe is the Fastest Growing Region for Clinical Trials Worldwide

In 2002, only 3.8% of all FDA 1572 forms were filed in the CEE region. Last year, the region represented double that percentage at 7.9%. Industry experts are in agreement that plenty of room for growth remains.



The number of global clinical trials initiated in Central and Eastern Europe more than tripled from 2002 through 2007, and approached 3,000 trials per year in 2007 (see figure).



Source: *The CenterWatch Monthly*, 2008 August

# Hungary is a Natural Gateway to Tap Potential for Clinical Trials in the Whole of Central and Eastern Europe

All leading global CROs and SMOs have offices in Hungary, including Covance, PPD, Quintiles, Parexel, ICON, i3, Kendle, PRA, Pharmanet and Synexus. A Hungarian-based regional CRO, Goodwill Research Ltd., was recently acquired by Pierrel, a mid-sized international CRO.

**Local and regional knowledge is key** as, although the EU Clinical Trial Directive was implemented in 2004, there is no uniform regulatory process governing the entire region, and each country also has its own local culture.

Regional clinical CROs with headquarters in Hungary are ideal partners to manage CEE regional trials.



*“The patient recruitment rate in Hungary was far beyond expectations compared to other countries. During the project, [our Hungarian CRO partner] was audited successfully without any major findings – leading to very good results. The work of [our Hungarian CRO partner] was a key contribution to the successful outcome of this project.”*

– Nuvelo, Inc., Sunnyvale, California

*“[Our Hungarian CRO partner’s] highly qualified staff comprises experienced, dedicated and professional individuals. We have never experienced any problems with the meeting of study deadlines, as [our Hungarian CRO partner] responded very quickly and efficiently to any requests made. They have proven the ability to simultaneously manage clinical trials in three different countries.”*

– Cancer International Research Group, Paris, France



*„[Our Hungarian CRO partner] is very reliable and offers a high-quality service. I strongly recommend them as a partner in clinical research.”*

– Lundbeck Hungaria Ltd., Budapest, Hungary

Source: Recommendation letter database of HungaroTrial Ltd.

## Clinical, Preclinical / Analytical CROs and SMOs in Hungary

The national CRO industry has its national growth drivers, too. Hungary's national pharmaceutical industry provides a wide source of accumulated knowledge in chemistry and biology. Uniquely in the CEE region, Hungary has over 70 enterprises focusing their activity on biotechnology-related R&D or manufacturing. In addition, there is a vast presence of large international pharmaceutical and biotechnology companies investing not only in sales and marketing but in local early and late stage R&D as well as manufacturing.

Regional Clinical CRO	Company Name	Offices in Other Countries	Founded	Website
	HungaroTrial Ltd.	Hungary, Czech Rep., Slovakia, Romania, Croatia, Serbia	1999	<a href="http://www.hungarotrial.hu">www.hungarotrial.hu</a>
Local Clinical CRO	Company Name	Countries Covered	Founded	Website
	Bitrial Ltd.	Hungary	2002	<a href="http://www.bitrial.hu">www.bitrial.hu</a>
	Trial Masters Ltd.	Hungary, Romania	2000	<a href="http://www.trialmasters.eu">www.trialmasters.eu</a>
Preclinical / Analytical CRO	Company Name	Additional Activities	Founded	Website
	Adware Research Ltd.	Data mgmt, biostatistics, QA, GLP-GCP audits	1997	<a href="http://www.adwareresearch.com">www.adwareresearch.com</a>
	Drug Research Center Ltd.	Monitoring, Phase I unit, SMO	1997	<a href="http://www.drc.hu">www.drc.hu</a>
	PharmaHungary Ltd.	Monitoring	2003	<a href="http://www.pharmahungary.com">www.pharmahungary.com</a>
	Pharmathesis Lp.	Data mgmt, monitoring	1991	<a href="http://www.pharmathesis.hu">www.pharmathesis.hu</a>
	Pro-Pharma Ltd.	Monitoring	1993	<a href="http://www.propharma.hu">www.propharma.hu</a>
SMO	Company Name	Additional Activities	Founded	Website
	ClinExpert Ltd.	Monitoring	2004	<a href="http://www.clinexpert.hu">www.clinexpert.hu</a>
	Ominis Research Ltd.	Monitoring	2007	<a href="http://www.ominis.eu">www.ominis.eu</a>

Source: Websites of companies as of October 2009

## Phase I Units Approved by the National Institute of Pharmacy

There is a high density of well-equipped Phase I platforms in Hungary.

Site	Location	Site Director	Phone
University of Debrecen Faculty of Medicine, 1st Clinic of Internal Medicine, Department of Clinical Pharmacology	Debrecen	Péter Kovács	+36 52 432 280
GR Goodwill Research Ltd., Pharmacoclinical Department, Szent Margit Hospital	Budapest	Géza Lakner	+36 1 436 0960
DRC Drug Research Center Ltd.	Balatonfüred	Éva Péterfai	+36 87 481 616
University of Pécs Faculty of Medicine, 1st Department of Internal Medicine, Clinical Pharmacology	Pécs	Tamás Habon	+36 72 536 145
National Institute of Oncology, Department "C" of Chemotherapy and Clinical Pharmacology	Budapest	István Bodrogi	+36 1 224 8600
1st Department of Internal Medicine, Szent Imre Hospital	Budapest	István Kiss	+36 1 464 8600
Semmelweis University Faculty of Medicine, 1st Clinic of Internal Medicine, Department of Clinical Pharmacology	Budapest	Judit Kapócsi	+36 1 459 1500
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University of Szeged, 1st Clinic of Internal Medicine	Szeged	Andrea Tiszai	+36 62 545 220
Semmelweis University Faculty of Medicine, 2nd Clinic of Pediatrics	Budapest	György Fekete	+36 1 215 1380
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National Institute of Oncology, Department "B" of Internal Medicine and Oncology and Clinical Pharmacology	Budapest	István Láng	+36 1 224 8600

Source: National Institute of Pharmacy, [www.ogyi.hu](http://www.ogyi.hu), and websites of hospitals as of September 2009



## ITD Hungary - A One-Stop Shop for Business

The government's investment and trade development agency was established in 1993 to promote inward investments and bilateral trade. With representative offices in eight regional centres of Hungary and a foreign network operating under Hungary's diplomatic services and by special assignments in 60 countries, ITD Hungary is a **single point of contact** to support decision-makers looking for new business opportunities in Hungary.

### For investors

- In-depth, **tailored information on the local economy** and the legal environment; sector-specific overviews
- Liaising with local and central authorities, suppliers and service providers
- Information and advice on **available incentives** and finalisation of incentives agreements
- Assistance in accelerating permitting procedures, recruitment and visa procedures
- Mediation between companies operating in Hungary and the government sector to **improve the business climate**
- Support and generation of reinvestments
- Promotion of Hungarian direct investments abroad

### Trade promotion

Through a diverse set of marketing tools and support programmes, ITD Hungary offers substantial **logistical, financial and professional assistance** to both

start-up and established Hungarian exporters. The Agency also co-ordinates the Hungarian activities of the **Enterprise Europe Network**, which, with a focus on innovative enterprises and innovation-related sectors, offers **support and advice to SMEs across Europe** and helps them make the most of opportunities in the European Union.

### Communication

The Agency arranges **business programmes** for individual visitors and delegations, and organises awareness and networking business events. ITD Hungary develops and distributes **printed and electronic business literature** in a variety of languages. Subscribe to ITD Hungary's electronic weekly Newsletter and/or order a free copy of HINT, its quarterly business magazine published in English and German, at [editor@itd.hu](mailto:editor@itd.hu).

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