

CLINICAL TRIALS

in Central and South Eastern Europe



Argint's **STEVE DOBBIN** discusses clinical trials in Central and South Eastern Europe

Argint International is a regional CRO based in Central and South Eastern Europe (CEE/SEE). **In which countries do you operate?**

We are currently actively managing and monitoring studies in Bulgaria, Croatia, the Czech Republic, Hungary, Romania, Serbia, Slovakia and Slovenia. We are also capable of conducting studies in Austria, Bosnia, Moldova, Macedonia and Montenegro.

Every year more trials are being placed in CEE/SEE.

How do you see the recent development of this market, and what does the future hold?

In the recent past, mainly phase III studies were placed in the region – often when they needed to be rescued due to poor patient recruitment elsewhere. As with all new markets, there was some initial trepidation on the part of companies to bring their studies to countries that were largely unknown and unfamiliar to them, even though some of the CEE/SEE

countries, such as Hungary, have had a long tradition of participation in clinical research. However, those companies that did place studies in the region had pleasant experiences – high patient recruitment and well-trained and compliant investigators who produced quality data.

Hence, the picture has changed dramatically over the past few years, and now companies are including sites in CEE/SEE from day one of their planning processes. As a result, we have also seen significant growth in the number of phase II studies coming to the region.

It is obvious that companies benefit from completing these early-phase studies quickly. The inclusion of high potential sites in CEE/SEE helps ensure results are obtained within target timelines and enables development programs to move forward into larger Phase III studies. We see the region as being particularly suited to these type of studies, and would advise pharma and biotech companies to consider supplementing the sites they choose in traditional 'target markets' with sites in CEE/SEE that will enrol patients

and help development programs progress quickly. Argint is in a great position to help U.S. or Western European companies integrate sites in CEE/SEE into their development plans.

The region will continue to develop and grow in the future, with more companies placing Phase II and III studies in CEE/SEE countries. There is a long way to go before a saturation point is reached. Other countries with untapped potential, such as Bosnia, Moldova and Macedonia, will also become more interesting to clients. We would be keen to help clients place studies in these countries.

What is the status of the CRO market in the region?

The region is complex in the sense that there are many small countries, each with its own language, culture and national regulatory requirements. For this reason, the large, global CROs have struggled to effectively set up their operations. Being able to claim a global presence is one thing, but being able to deliver excellence in all regions is very difficult to achieve. CEE/SEE is a region better suited

to small, agile CROs like Argint that have the local knowledge and flexibility to set up and operate on a regional level. It really is difficult to manage studies effectively from outside the region—as many of the global CROs attempt to do. It helps to have experienced project managers based in the region who are familiar with local requirements and cultures.

In addition to the sometimes patchy coverage provided by the global CROs, there are many small CROs providing services in one or a few countries. The quality varies considerably – some are very good, while others have been set up and are run by people with limited experience of international clinical trials. Argint is unusual in that the senior management has extensive experience of managing clinical trials throughout the world to international standards, while at the same time having the local connections and expertise to conduct trials in CEE/SEE. My own history involves living and working in Europe, the U.S. and Asia Pacific while managing global trials. Agnes Pinnel, CEO of Argint, previously established the regional office in CEE for one of the top five CROs. Agnes lived

and worked in Western Europe for many years but is originally from Romania. She also speaks eight languages fluently, including most of the languages spoken in the region. Argint currently has a mix of CRAs who are fluent in a total of 12 CEE/SEE languages, and we are able to manage and monitor studies throughout the region.

Some people are intimidated by the complex nature of the region – there are many small countries, numerous languages and cultures. Why would you recommend companies to place studies in CEE/SEE?

The total population Argint can access is approximately 90 million people in 13 countries. That is a considerable market. Individual country populations range from 600,000 people (Montenegro) to 23 million (Romania). Provided companies are willing to take advice and guidance from local experts, it is as easy to set up and run trials in this region as anywhere else. Companies benefit from access to patients who are willing to participate in clinical trials. Patients can be found easily, as the healthcare

system remains highly centralized in these countries. Some of the largest hospitals in Europe are found within the CEE/SEE region. As there are relatively few family doctors, patients with particular conditions generally go directly to hospital specialists for treatment. Hence, recruiting patients into clinical trials is much easier—we recruit investigators who are specialist physicians seeing and treating almost all the patients with the particular conditions in the city or county. For example, countries such as Slovenia, with a population of 2 million people, are often overlooked by pharmaceutical and biotech companies. However, if a few sites are opened in Slovenia, access is available to almost every patient in the country who is suffering from a specific target condition. In addition, the Slovenian regulatory agency and central ethics committee is among the most efficient in Europe.

In addition to the general long-term savings available to pharma companies and biotechs that come from completing recruitment into studies earlier, there are also more immediate savings available. Local and regional CROs within CEE/SEE generally charge competitive fees for their services.

Combining Global Experience with Local Expertise

CRO services in Eastern Europe

- Feasibility
- Regulatory & Ethics
- Project Management
- Monitoring
- Contract CRAs
- Consultancy

Access to Patients • Cost Effective • Quality Focused

Tel: +36 70 320 2870 • Fax: +36 1 274 0213 • E-mail: enquiries@argintinternational.com • www.argintinternational.com

“THE TOTAL POPULATION ARGINT CAN ACCESS IS APPROXIMATELY 90 MILLION PEOPLE IN 13 COUNTRIES. THAT IS A CONSIDERABLE MARKET.”

What is the regulatory landscape like in CEE/SEE? How does Argint support regulatory and ethics submissions within the region?

Most of the countries in CEE/SEE are now part of the European Union and follow the EU Directive on clinical trials. For EU countries, there is a core set of documents required for all submissions and a common application form for both regulatory and ethics submissions. Those that are not yet part of the EU, such as Serbia, have already brought their national legislations in line with the EU Directive as preparation for future membership. The French regulatory agency has worked extensively with the Serbian agency and provided it with support and advice as it develops its local legislation and internal processes. The Serbian agency is very efficient, and its processes are in line with the EU Directive. In addition to core documentation, such as the IMPD, protocol and drug labels, all CEE/SEE countries also require additional country-specific documentation to be collected and submitted to the agencies for review.

In general, we would expect to have regulatory and ethics responses within 60 days of submission in all CEE/SEE countries. Some countries are a bit faster. For example, Slovenia and Serbia routinely review studies in less than 60 days.

Dr. Eva Halasz, Director of Clinical and Regulatory Compliance at Argint, leads Argint's regulatory services team. Dr. Halasz coordinates and supervises all regulatory and ethics submissions made by Argint. Dr. Halasz is familiar with both

EU and local national legislation relating to clinical trials procedures in Argint's countries of operation. Country experts within the team prepare and collect documentation required for submissions from participating investigators and hospital directors. Argint's regulatory team is also familiar with the preferences for wording of study documents, such as patient information leaflets, that ethics committees may have. These are often not written down anywhere, and this knowledge can only be gained from experience.

Dr. Halasz regularly receives positive feedback from agencies on the quality of the documentation that Argint's regulatory services team produces and submits for review.

To summarize: Argint is fully capable of supporting regulatory and ethics submissions throughout CEE/SEE, and we routinely provide this service to our clients.

You mentioned that Argint is an 'agile' CRO.

What do you mean by this?

Argint is a small company compared to the large, global CROs. We have the advantage of being able to reinvent ourselves very quickly, adapt our systems and processes to meet the needs of our customers and employees, and also respond to changes in the local markets. We can be very flexible and can enter into working arrangements with clients that large companies may struggle to reconcile with their internal policies and procedures.

We are innovative and good ideas are implemented. There is no bureaucracy in the decision making process and no resistance to change. This enables us to continually improve our working practices and processes to increase efficiencies and our quality of service. The people working with our internal SOPs and forms are the agents of change providing feedback on usability and suggestions for improvement.

We are able to embrace new technologies that suit the mobile working patterns of CRAs. We have a completely mobile workforce. We were the first company in Hungary to have a fully integrated telephone system based exclusively on mobile telephones and the first company to acquire 'Hotboxes' (a UK design-award-winning storage unit) to facilitate nomadic working patterns. In addition, we have implemented centralized hosted email and data storage that enable our employees to access our systems from home or from hotel rooms as effectively as if they were sitting in our office. Our infrastructure is based on cutting-edge technologies that big companies simply cannot employ due to size and the existence of older legacy systems that will not integrate with newer technologies. This produces efficiencies in performance that give Argint significant advantages over other CROs.

Argint will remain focused on delivering high quality, regional CRO services to our clients. We will continue to embrace new technologies to enhance our productivity.

We do not want to be the biggest CRO in the world – just the best. **FP**



STEVE DOBBIN, COO and Co-Founder, Argint International, a regional CRO based in Central and South Eastern Europe, is responsible for development of Argint's operational processes and remains closely involved with oversight of projects. Steve has worked in the industry for over 17 years, and during this time has been based in Europe, North America and Asia-Pacific.

House ad