

Leader of the Emerging Markets

a report by

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Pharm-Olam International (POI) has distinguished itself as a pioneer in the clinical research industry for the past 10 years. Significant revenue growth has evolved from POI's transcontinental presence and a highly-experienced network of medical professionals in global emerging markets. POI is a proven leader and a true multi-national contract/clinical research organisation (CRO) that consistently delivers the highest quality data, achieves targeted enrollment requirements and meets projected timelines, all within a very competitive budget. Their corporate objective is to exceed the increasingly demanding requirements and expectations of the pharmaceutical and biotech industries.

A decade ago, the world of clinical trials was a very different place. Western Europe and North America were considered the hub for conducting clinical trial ventures. More recently, Eastern Europe emerged from the yoke of communist regimes and, until now, was unexplored territory for clinical trials and CROs in particular. Latin America, Asia and Africa were not considered as viable trial locations by the conservative outsourcing departments of most pharmaceutical companies.

As a CRO seeking to establish an identity or 'footprint' by offering a different standard of services from the usual, POI quickly realised that the advantages of Eastern Europe were significant. Not only did Eastern Europe provide a surplus of treatment-naïve patients across a broad range of therapeutic areas, but it offered highly qualified and dedicated investigators who were eager to participate in multi-national trials. In addition, the costs of conducting trials were significantly lower than in Western Europe or North America, and patients were anxious to gain access to 'Western' medicines.

However, Eastern Europe had more to reveal. POI discovered a prevalence of major hospitals, specialists and out-patient clinics, all of which consolidated a large number of patients with specific health conditions in countries with huge populations.

Initially, some disadvantages were also found. The investigators' lack of experience in international

clinical trials, absent experience in good clinical practice (GCP), poor informational technology (IT) infrastructure, government bureaucracy, uninspiring approval timelines and a deficiency of experienced clinical research associates (CRAs). While medically qualified (CRA trainees were readily available at comparatively low salary levels), these doctors required rapid and thorough training, in addition to acquiring some intensive, practical monitoring experience.

In 1995, POI conducted its first clinical trial in Poland for a Spanish pharmaceutical company. The study was managed from POI's UK headquarters in Ascot, Berkshire. During the mid-to-late 1990s, POI established offices in Warsaw (Poland), Prague (Czech Republic), Moscow (Russia) and Sofia (Bulgaria).

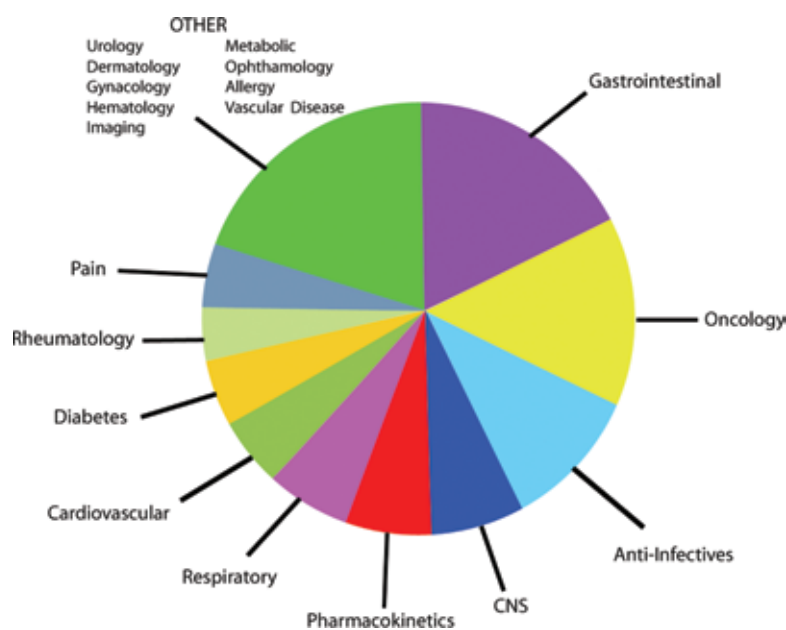
A majority of POI's sponsors were either British or US-based companies. As such, project management functions remained in POI's European headquarters in Ascot, because sponsors preferred to have their studies managed by a professional whose first language was English.

The first four years of the new millennium witnessed POI's rapid growth, primarily from repeat business by existing and previous sponsors. POI successfully managed a large number of 'rescue' trials when studies conducted by the sponsor (using in-house, clinical trial departments or utilising the services of other CROs in North America or Western Europe) failed to meet patient recruitment targets, and were under internal marketing pressure to meet initial product development timelines. POI launched study sites in Central and Eastern Europe to rescue trials for several sponsors.

These rescue missions confirmed POI's ability to provide high-quality, statistical evidence demonstrating their high patient recruitment success within Central and Eastern Europe. Prior to these rescue trials, POI always had to produce evidence for existing and prospective sponsors to exhibit its claims that the data produced on trials in Central and Eastern Europe were of high quality.



Figure 1: POI's Experience Encompasses all Phases of the Drug Development Process and all of the Major Therapeutic Areas



Sponsors who had no experience conducting trials outside North America or Western Europe had reservations and pre-conceived ideas about the quality of data they would receive if they were to outsource clinical trials to a CRO operating in this area.

During its infancy, POI utilised the services of part-time CRAs and of small, local CROs in countries where it was not economical for POI to create its own subsidiary. In time, both were replaced, as POI created its own offices in Belgrade (Serbia and Montenegro), Budapest (Hungary), Kiev (Ukraine), Zagreb (Croatia) and Bucharest (Romania). POI employed its own dedicated monitors in Estonia, Georgia, Bosnia-Herzegovina and Macedonia. All POI staff in these locations speak English with a high degree of competency and fluency. Local project management services have also been developed and utilised in a number of POI's major offices.

Over the past two years, many North American and/or Western European-owned or -based CROs, who operate solely in these territories, have recognised the advantages of having their own operations in Central and Eastern Europe. Most have now established offices in various countries within the region. Because POI's coverage was already well established in these areas, they were successfully managing trials for sponsors for various reasons including rescue studies, marketing or to include 'opinion Leaders' in studies.

POI has expanded its operations into Western Europe and North America, by opening offices in Munich (Germany), Milan (Italy), Madrid (Spain) and Brussels (Belgium) to complement its established

European headquarters in Ascot, UK and its global headquarters in Houston, Texas.

Study approval timelines have improved dramatically over the decade. In some countries, outside the EU, approval can be expected within six to eight weeks. POI's record for trial approval was set in Serbia and Montenegro where a trial was approved in 19 working days.

Concerns about the political stability of countries in Central and Eastern Europe have proven to be of no substance. In May 2004, the Czech Republic, Hungary, Poland, Estonia, Latvia, Lithuania, Slovakia and Slovenia joined the EU. Serbia and Montenegro has emerged from the days of turmoil to become a prominent country in which POI conducts clinical trials. POI is currently conducting one-third of all clinical trials in Serbia and Montenegro.

Having established itself as the leading CRO in Central and Eastern Europe, POI is examining the feasibility of conducting clinical trials in other emerging markets. Its objective is to explore the possibilities of utilising large pools of treatment-naïve patients in these countries to conduct studies for prevalent diseases/conditions. This will enable POI to offer trial sites located in the Southern hemisphere for conducting seasonal trials for multiple sponsors.

Latin America is an area included in many international trials. POI has conducted trials in Brazil and Mexico. It opened an office in Mexico City earlier this year. POI has also expanded into Africa and is currently conducting a major trial in South Africa.

Sponsors have expressed an interest in Asia (in particular India), with its appealing populace, over the last few years. India, with more than one billion inhabitants or one-sixth of the world's population, offers enormous potential for the successful management of clinical trials. POI has expanded into India and is currently conducting a major international study in multiple sites throughout the country. An office in Bangalore was opened two years ago, and the Indian operation has become a successful contributor to POI's reputation and range of services.

The company meets the same challenges in India of convincing sponsors of the quality of data produced with clinical trials as it has faced in the past when introducing sponsors to Central and Eastern Europe.

China, the major economic powerhouse of the Eastern hemisphere, and potentially the global economic leader of the next 50 years, is currently

being explored by POI, along with operation possibilities in Taiwan, Thailand, Japan and Australia.

All current forecasts show that the percentage of clinical trials being outsourced will continue to increase. The perception of outsourcing within the pharmaceutical industry has changed from being a solution of dealing with short-term capacity problems to being a strategic business tool. In the US, the pharmaceutical outsourcing business is forecast to increase to US\$48 billion from current values of US\$30 billion by 2008.

Pharmaceutical and biotech companies now use CROs for more than 60% of their clinical projects, and CROs accounted for about 20% of research and development (R&D) budgets at biotech and pharmaceutical companies in 2003. Escalating costs of drug development will, however, place increased emphasis on every aspect of CROs' performance.

With an emphasis on quality and rapid patient recruitment, POI is ideally positioned to meet the requirements of the pharmaceutical and biotech industries over the coming years. ■
