

White Paper
CLINICAL RESEARCH IN POLAND
AN INTRODUCTION



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1. Healthcare Landscape in Poland

Poland is a country in East-Central Europe with a population of about 38 million people. After the Polish accession to the European Union in May 2004, the legal and administrative framework to implement the EU Directive on Clinical Trials was enacted, just as in all other member states.

Joining the EU has significantly contributed to a change in the perception of Poland as a suitable place to conduct clinical trials. Sponsors include Poland because they benefit from a regulatory environment which is standardized and predictable, whilst maintaining the advantage of lower cost and higher subject recruitment potential.

2. Clinical Research Activity in Poland

In 2013, 407 applications to perform a clinical trial with a medicinal product were received by the Polish Competent Authority¹, which the report state is down approximately 10% from the figure for 2012. The decrease probably reflects the growing competition in the clinical trials marketplace from the new emerging markets, including those in Asia. Nevertheless, the total market size in Poland is considerable, with PwC estimating that the Polish clinical trial market was worth approximately 860 million Polish zlotych (200 million Euro)², making Poland the largest market of clinical trials in the Central Eastern European region, conducting approximately 20 % of all trials.

The relative lack of local in-house clinical research infrastructure of sponsor companies choosing to include Poland in their projects is illustrated by the fact that most studies in Poland are managed by CROs (70% in terms of volume and 53% in terms of value). Additionally, both the number of patients involved in clinical trials, and the number of centers where trials are conducted indicates significant growth is continuing. Data shows that at the end of 2011 there were 449 trials conducted in Poland and the number of studies (including non-commercial research) started in 2012 in Poland changed to 326 (data from ClinicalTrials.gov). Poland holds the tenth position in the world and first among emerging markets in terms of the number of clinical studies as well as the 7th place in Europe in terms of the number of patients participating in clinical trials (according to the Association for Good Clinical Practice in Poland). About 40,000 patients participate in clinical trials in Poland each year. The year 2008 was a record year for our market, with 51.4 thousand patients enrolled.

The three main factors influencing decision making in clinical trials are typically time, cost and quality. The success of Poland as a location for clinical trials results from advantages which are present in all three of these factors.

Enrollment to clinical trials in Poland is typically faster than in many other countries. This may be due to a number of factors, which are described below.

Firstly, Poland has a relatively large population in comparison with neighboring countries.

Secondly, the presence of specialized medical centers clustered around main cities (e.g. Warszawa, Wrocław, Kraków, Poznań, Szczecin, Gdańsk, Lublin, Bydgoszcz, Rzeszów) provides access to patients in all therapeutic areas, particularly oncology, rheumatology, cardiology and pediatrics. Indeed the number of hospitals and healthcare facilities is considerable – the Polish Central Statistical Office (GUS) report that Poland has 800 hospitals and 16,600 outpatient facilities.

There seems to be a greater motivation for patients in Poland to become involved in clinical trials, compared to mature Western European markets. This is because patients participating in trials in Poland usually have access to medical treatment of a higher level than is the case of standard care. Patient recruitment for clinical trials in Western European countries is difficult as people have either access to good medical care from government hospitals or they have medical insurance which provides immediate treatment in a private facility. However in Poland, access to the national health system is limited and medications are expensive, and hence, with the offer of better medical care, free drugs and diagnostic procedures, patient recruitment in clinical trials is very high. This factor is particularly important when treating patients in areas where the availability of effective drugs is limited at this stage of the development of medicine (i.e. oncology or transplant treatment).



Oncology, for example, is a frequent area of clinical research in Poland, because it is relatively easy to find patients in Poland in the late stages of the disease. This is not as simple in many countries in Western Europe. In fact, approximately one third of patients in clinical trials in Poland are enrolled in oncology studies. The high motivation to be involved in clinical research in Poland may also result from the relatively long time patients may have to wait to see a specialist in Poland. Participation in a clinical trial therefore significantly shortens the waiting time associated with receiving specialist care. Furthermore, it may be the case that subjects can access medicines through clinical trials which are not typically available in Poland.

The increased benefits for patients participating in clinical trials in turn leads to highly motivated investigators, as they can see the benefits in the work they do more than their colleagues in Western countries. It should also be noted that in addition to purely economic stimuli, clinical trials are attractive to investigators because of possibility to test new treatment standards, exchange information with foreign experts and the opportunity to have co-authored publications in respected branch magazines. According to experts, Poland

is the favored destination for clinical trials because of the investigators and support staff. They have over 20 years of rich experience in conducting of the research that pays off in the quality of the data that is provided by medical personnel. It is worth noting that no Polish investigator is present on the FDA's list of disqualified investigators.

Poland holds a strategic advantage in the cost of conducting clinical trials and is much cheaper than in the U.S. The cost per trial in Poland is nearly 30% less than the cost in the U.S. The costs of a clinical trial conducted in Poland are relatively low due to a high rate of patient recruitment and excellent quality of data, leading to a reduced number of rejected clinical trials recordings and time-efficient proceedings. The comparison of the number of U.S. Food and Drug Administration (FDA) audit site inspections carried out between 1997 and 2008 in various countries worldwide showed that Poland has a high standard of clinical trial procedures and provides good quality clinical trial data (GBI Research, Primary Research).

A key challenge for the Polish clinical trials market is shortening the time and standardization of administrative procedures regarding signing of clinical trial agreement



with the sites, which may differ regarding on the type of the site. Small, private sites usually are very easy to sign contract with, whereas large hospitals, as a part of national healthcare system, tend to have additional, specific requirements. At present, most large public centers have introduced rules on collaboration between sponsors / CROs and centers and posted these rules on their websites, which

improved i.e. efficiency of contract negotiations. In this context it is also worth mentioning that CROMSOURCE has never failed in negotiating and signing a contract with a site selected for conducting a clinical trial. Most centers have set up study coordinators in order to improve contact between the centers, investigators and sponsors / CROs. The submission process proceeds in parallel at the Central Authority (Office for Registration of Medicinal Products, Medical Devices and Biocide Products) and Bioethics Committee. Timelines are similar to those in other European countries. With respect to the Bioethics Committee, some committees have their meetings on demand when the study is submitted. Most, however, have meetings on a monthly basis, with documents to be submitted at least 14 days before the meeting. All the substantial amendments are approved within 35 days.

3. Conclusion

With high levels of subject recruitment, high data quality and committed investigators, and relatively low costs, Poland is an attractive location for clinical research. Furthermore, the fact that that the regulatory and administrative situation is comparable to other countries in Western Europe ensures that start up activities can be completed efficiently.

CROMSOURCE has been delivering clinical trials in Poland since the year 2000 and our depth of local experience and expertise provides our sponsors with the knowledge that when electing to include Poland within their clinical studies a successful outcome is assured.

4. References

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5. About the Author

Krzysztofa Łuczak-Szymerska, Associate Director of Project Management Department, CROMSOURCE.



Krzysztofa joined CROMSOURCE as a Country Clinical Research Coordinator in May 2006. Since that time, Krzysztofa has held several roles of increasing seniority, responsible for the operational aspects of project management and delivery. Initially on the country level (Poland), then globally for European countries. In 2009 Krzysztofa completed Postgraduate studies in Methodology of the Clinical Trials at the Medical University of Warsaw (Poland) and in 2013

became the Associate Director of the Project Management department with responsibility to support the Director of the department for overseeing project management and delivery of all CROMSOURCE clinical projects. Krzysztofa may be contacted at krzysztofa.luczak@cromsource.com.

6. About CROMSOURCE

CROMSOURCE is a high quality ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialized in clinical development and staffing solutions.

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