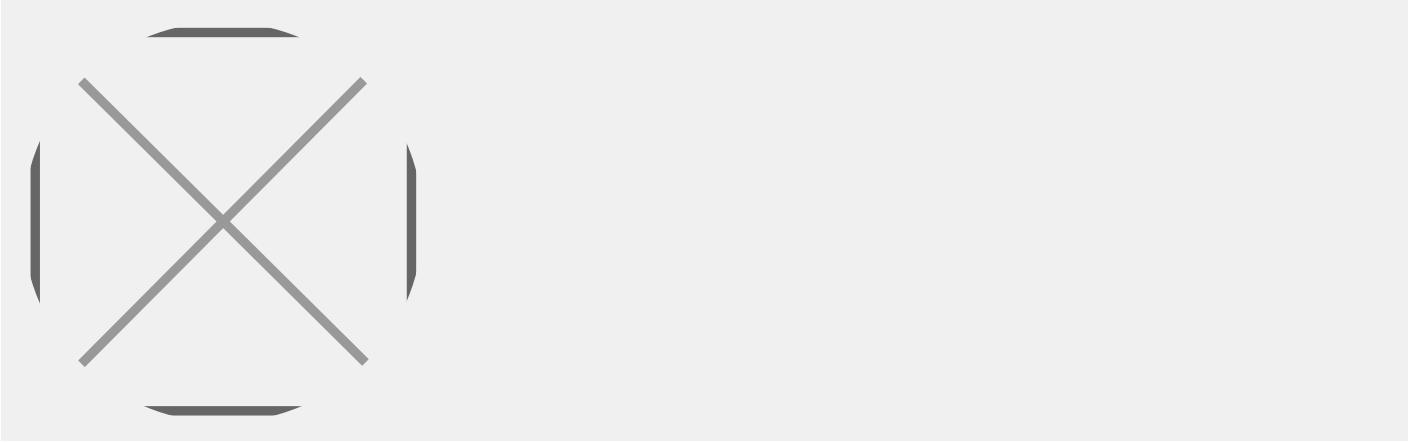
Interview with Wojciech Przybys, Vice President Northeastern Europe, Quintiles Poland



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Firstly, what attracted you to join the CRO industry with Quintiles over 10 years ago?

I had been working for 5 years as a doctor in the internal medicine and intensive care departments of the Warsaw medical school. The team there was already conducting some medical research in the clinic. Personally speaking, I found it extremely interesting to work on new drugs and medical treatments outside of the hospital. In a hospital you have the capacity to help 100 to 200 patients depending on the size of the ward. If you help to develop a drug then your influence can extend to thousands or even millions of patients. This was the attraction to join the CRO industry.

Medical doctors are uniquely positioned to be CRAs because they understand the needs of patients and the reality of hospitals. As a CRA, I feel extremely privileged to be able to work in a true multinational environment with a real say. When I began in the CRO industry the teams were small meaning that each individual team member was important and this was extremely motivating. This is a philosophy we maintain to this day.

The Polish pharma industry seems to be dominated by former doctors. Do you believe this is now part of the industry culture?

I think many former doctors had a similar motivation to me in wanting to extend their influence on the lives of patients. However, it is not conditio sine qua non to be a doctor in the top management of the Polish pharma industry. Indeed there is such a mix of operational duties, people management, customer relations and dealing with different stakeholders that whoever is in charge

needs to be highly adaptive. It is true that doctors who end up interacting with former colleagues and fellow medical professionals have some advantages in terms of understanding. The key disadvantage of course is that they do not have the economic background.

Moving on to the development of clinical trials, what would you say were the factors shaping its evolution in Poland?

As their primary function, clinical trials should exist to help patients. The end goal is to create treatments which are safer and more effective.
In terms of the factors which have shaped the Polish context, the pressure on the government to conduct trials has changed dramatically with the social media. Looking at what happened recently with the political upheaval in Egypt, gives an insight into today's empowerment of people using social media to drive political change. Consequently, patient associations have become more powerful and their calls are better heard by politicians when they ask for safer more effective medications.

The second factor influencing the development of clinical trials is the transformation of Poland following European Union (EU) accession. Seven years ago the country joined the EU and had to adopt European medical standards and legislation.

The third factor was an increased willingness of the Polish principal investigators to be more active in the international environment. This has encouraged clinical trials to take place in Poland. In addition, one of the advantages of Poland is the time that medics are actively evolved in the study. The Polish CRA spends twice or even three times longer with physicians than in other parts of the world. Because of this contact time the CRAs are able to learn a lot about medical regulations and similarly doctors can benefit from experience in clinical research.

You are now the Vice President of North Eastern Europe for Quintiles and have experience running the CRO's offices in 7 different countries. What is the significance of Poland as a destination for clinical trials?

Poland is the biggest single country in the region with a current market share of around 18% of clinical trials. One of the main reasons these trials occur here is the size of the population; 40 million is a significant number for finding patients for clinical trials. In fact, when 10 countries joined the EU in the big bang accession of 2004, Poland brought in 50% of the new EU citizens.

In terms of the market for drugs, Poland is in 6th/7th position in Europe and of comparable size to the Netherlands. So whilst, Poland is not the biggest, it is a very important market and it is growing. Your title: 'The sleeping giant' may be an appropriate label for Poland. In the last two years when the economy was in recession Poland was the only country to continue in economic growth.

Michel Abiteboul of France told Focus Reports in 2009 that clinical trials were moving to Eastern Europe because of better patient recruitment. However, given that other countries such as Ukraine and Russia are developing in clinical trials, can Poland maintain its prominent position in the region?

In the long run, 10-20 years, Poland will most probably lose its prominence compared to Russia, the Ukraine or even China and the rest of Asia. However, in the short term, Poland continues to lead. It should be noted that given the state of the pharmaceutical market at the moment the industry tends to have a short term perspective.

Thinking about Quintiles' concept of the world of 'New Health' the trend within the pharma industry has been towards ever increasing complexity. Today there are more stakeholders, there are the patent cliffs affecting big pharma, there is greater focus on regulatory affairs because of concerns over safety. There is increasing patient pressure and the insurance companies are more and more involved in the process of reimbursing drugs. This is therefore a very complex environment and Quintiles is really uniquely positioned in helping its customers to succeed in this environment.

Poland offers excellent value for money and the high quality data . This has been documented by a number of external sources as well as internal surveys. In general data coming from Eastern Europe is some of the highest internationally. Such data quality helps to ensure the safety of the patients and increases productivity because if the data does not need to be justified or amended then this saves on time and resources.

In terms of the number of patients per site in Poland against the average internationally the country does very well. Poland is looking to double these numbers. This helps the principal investigators to be more productive and essentially by dealing with more patients they are able to improve on their procedures. There is a Latin proverb: "repetitio est mater studiorum" (repetition is the mother of learning), the more you repeat the more you learn.

Ultimately, Poland is the answer to the executive who wants excellent data and an attractive cost.

You mention the New Health environment. How can Quintiles help companies to adjust?

At Quintiles we believe innovation must be at the centre for the next few years. The traditional model of developing, marketing and selling drugs no longer works. This is where the portfolio and experience of Quintiles is allowing companies to find solutions which are attractive to customers. Quintiles has the expertise, data driven solutions and flexibility to really tailor its offer to fit customer needs.

Quintiles has 4 main offerings from clinical trials to assisting in market access. How would you describe the balance of your focus across these areas?

In Poland most of the time and resources are dedicated to the clinical part. However, there are emerging opportunities to develop the commercial, consulting and capital divisions. The company has not yet developed these tasks fully in Poland but they will provide opportunities for further growth.

In 2009 PWC identified 4 possible trends for clinical trials Poland ranging from a depression of the market to positive growth depending on legislation. What is your level of optimism regarding the level of regulatory legislation in Poland?

I am quite optimistic for a few reasons. Regulatory affairs have no doubt been challenging, however, although the start up times for clinical trials have been extended, they are still around the same as European averages.

There is now much more cooperation between the government agencies and the CRO industry than there was over the last 2-3 years. It was understandable that the government initially focused on the big topics and clinical research was not the priority concern. The main idea was to define the laws and improve the financing of the healthcare sector. Now the time has come to look at clinical research. The government appears willing to achieve the goals of CROs in maintaining safety but shortening the timeframes for conducting trials.

With the status of Quintiles as a market leader within Poland to what extent are you able to shape the development of the clinical trials industry in Poland?

As with many so called emerging markets, Poland has travelled a long distance in its development. Previously there was not much structured cooperation among stakeholders and this has all changed today. Quintiles has been at the centre of developing such collaboration. A few years ago Quintiles was a key contributor in a training session organised by the Warsaw medical school teaching regulatory inspectors how to perform inspection.

Quintiles is in fact the most often audited CRO in Eastern Europe. In the last 6 years Quintiles has had 144 audits and inspections. Last year Quintiles had 37 audits and inspections. Therefore excluding the holidays, there was an inspection every week. This gives Quintiles key insights into how the EMEA and FDA inspectors are analysing the situation. This puts Quintiles in a unique situation to share this knowledge with investigators.

Last year Quintiles also produced a book and distributed it to all investigators within Poland. It is a summary of Good Clinical Practice, European directives and Polish acts referring to clinical studies. As an investigator you are a doctor and not a lawyer. If you have to look at 10 different documents to know what to do in a certain situation it can be very time consuming. Quintiles did this to help these investigators find answers to daily questions.

The future of the clinical research industry lies in centres of excellence which will conduct many studies and will have dedicated resources to treat patients. Quintiles is now working actively to help our clinics and partners to develop in this direction.

To shape the market there also needs to be excellent talent. The employees of Quintiles are of extremely high skill and education. 98% have higher education. 100% of staff who had direct contact with investigators have been certified by a third party as passing good clinical practice tests. These highly qualified people are also working to shape the Polish market.

Therefore, in legal affairs, in sharing information about inspections, in developing partners for the future and in promoting high level human resources, Quintiles is helping to shape the industry in Poland.

As a final message, having attained a #1 position in Poland and in Central and Eastern Europe, how is Quintiles going to stay there?

As I said at the beginning, better medication and safer treatment for patients should drive the industry. The future for the industry is specialised clinical research sites where well-equipped, well educated staff are present. The industry revolves around three pillars: safety, productivity (lower cost) and quality. This is exactly the focus of Quintiles in providing the highest quality data, safety for patients but at attractive and competitive costs.

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