Interview with Petr Janda, General Manager, ACRO Czech Republic

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ACRO Czech Republic

se begin by introducing our readers to the ACRO-CZ, and explicate its mission on this market?

Mimicking the European standards, we also wanted to connect all the national associations so in the 1990s we created ACRO-CZ that had only four or five members. We started to negotiate with Czech authorities and gradually, we started running a GCP teaching program. This was made possible thanks to a grant of 400.000euros from the European Community. Following this, almost all CROs became our members but obviously we needed to apply the necessary regulations and code of ethics. Today, we have approximately 30 members some of which are foreign CROs.

There is a long history of why Czech Republic is such a popular spot for clinical trials. During communism, there were some privileged hospitals such as IKEM, an experimental hospital that conducted clinical trials. This was exceptional among the ex-Soviet countries. Moreover, after the Velvet Revolution in 1989, there was a lot of material and good technology left so Czech doctors were very eager to join the trials which stood in an opposition to the West where the medical community was becoming tired of it. The enrollment rate was higher and fees were lower than in Western Europe.

Also, it needs to be said that the Czech Republic is really in the middle of Europe. Companies wanting to carry on studies in Eastern Europe would usually come to Prague, set up an office and direct it from here.

However, the situation is changing now like everywhere else. Unfortunately, I would not be very optimistic. The physicians who used to do a lot of clinical trials became uninterested and this situation is now similar to the one in France or Germany. This means that the doctors are not working for free as they did before because it was so interesting to them.

The investigator fees in the big hospitals are now priced exactly the same as in Western Europe so there is no advantage left. One advantage that remains lies within the scope of smaller GP offices and outpatient departments. For example, if you are looking to do a clinical trial in dermatology, you would go to outpatient unit where you should still be able to negotiate a price that would not be possible in Western Europe. For the large indication studies, such as oncology, the situation is like in Western Europe.

Another thing that is still better here are the monitoring fees. They are still 20-30% cheaper than, for instance, in Germany. It is not like 70% during 1990s but it is still beneficial to come here. Enrollment

rates also remain high which is good. It is also very good that the companies are staying in Prague. Moreover, I want to highlight that our physicians are still very open and operational and the quality of data is one of the best in Europe.

Why do you think the enrollment is still very high in the Czech Republic?

I do not think that it has to do anything with drug availability since we have the same portfolio as Western Europe. If it is an innovative drug Phase III, obviously everyone is eager to have this. I would say that the enrollment on large indications is the same as elsewhere but for smaller indications, the clinicians are actively looking for participants. I remember one dental study where the doctor created a net of other practitioners sending him patients for his study. Unfortunately, I do not think that this will last for a long time.

If this becomes the case, will the Czech Republic be still able to maintain the high volume of clinical trials per capita? You see that France or the UK are pulling trials back home and also exporting the trials to countries such as India or China. Do you think this is the way to go for the Czech Republic?

I have been doing this job for twenty years now and I have a feeling that in five years we will be, unfortunately, facing the very same problems. There will be no real advantage to come to the Czech Republic. It will remain to be a good destination for clinical trials, with high expertise but in terms of enrollment rates or financing it will become the same.

In the beginning of 1990s the large companies spread east because it was beneficial. In 2000 they slowly started coming back home and this is exactly because there are not real advantages anymore. It is also going to be a question of proportionality. For instance, in Russia, you need to run at least some portion of the research in the country in order to be able to register a drug there.

In terms of BRIC and other developing countries, it is good to turn to them but I have a personal feeling that the timing for this is over now. For us it is more Moldavia, Georgia and other post-Soviet countries that could provide us with clinical trials. However, in order to carry out a study in such a country, you usually need to have a very strong quality management. Here, in Czech Republic, we carry on quality auditing on a trimester basis but in these countries, you would need to do that every month.

It is still cheaper to go there but because of this and the fact that often you need to provide their hospitals with the material, I do not think that in four years we will be outsourcing our clinical studies there. Overall, it could turn out to be more expensive. However, it is extremely interesting to go to these countries especially if you are looking for certain indications that you cannot find in the Czech Republic such as non-treated hypertension or non-treated endocrinological conditions.

Another example would be India where in 2009 there were an essential number of clinical trials, mainly Phase I, have been rejected by the EU authorities because of the GCP problems. This was a breaking point where a lot of companies decided against taking their trials there. I saw some of the results of phase II and III from India and none of them were admitted to Europe. In conclusion, if you want a high-quality study and results you should think twice and plan very well ahead.

Shifting to the current regulatory framework in the Czech Republic, SUKL is the regulator here. What do you communicate to them as an association lobbying for CROs? What do you think is good about the regulatory environment and what would have to be changed?

Here in ACRO, we have multiple special committees such as a special committee for the Phase I or a special committee for pediatric studies. We are on the mailing list of SUKLâ??s collaborators so

every proposal or meeting announcement coming from their side is also reaching us. We then discuss the proposed changes and developments internally within ACRO and then we proceed with personal meetings. Our working group specialist will meet with the counterparts from other associations and go discuss the proposed regulations with SUKL. I must say that, historically speaking, SUKL is one of the most progressive and best regulatory bodies in the CEE. Of course, like every authority they are bureaucratic and can take time to react but on the other hand, SUKL is still keeping the high level of knowledge about clinical trials.

I remember that once when discussing timing of approvals for the Phase I, one of our working groups wrote a letter to SUKL and SUKL fully accepted what we proposed and changed the decree for the procedure accordingly.

Conversely, what benefits do you see for the Czech patient and Czech government when innovators chose to conduct trials here? Mr. DvoÅ?Ã¡Ä•ek, for instance, noted that clinical trials in 2010 covered approximately 3% of the yearly budget for oncology and cardiovascular disease.

I am not able to give you any exact figures as this is not part of our work but I know that there is a lot of money going to hospitals. The question, then, is about the distribution of these funds since it is known that large hospitals with clinical trials are taking approximately 70% of the budget.

What is the role of CROs in running clinical trials? To what extent do pharmaceutical companies do it themselves?

I would say that in the Czech Republic, there is only a very limited number of pharmaceutical companies with their own CRO unit that would be able to complete a study from the beginning to its end. Furthermore, even the big companies are not able to do this at the moment. In this vein, CROs are very important here. All of them need CROs at some point. The percentage of CRO involvement in clinical trials is much higher here than in Western Europe. This is because the Czech Republic is only holding the branch offices and not the headquarters of these companies that often are large enough to carry on the trials.

What future do you see for your members during the next two years? Do you think the market will grow?

I am sure it will. I think that we can do even more trials. There are a lot of generics coming to the market which opens the door for more trials. After that in five to ten years, I am afraid the market will become saturated like in Western Europe. It also depends on what the economic situation will be.

On a personal note, you have been the director for the ACRO for more than two decades. What keeps you interested in fighting for these issues?

I still think that it is a very interesting work to do. Also, I need to say that it is a wonderful feeling when you get positive results out of a clinical trial or a study. I am a doctor myself with a long experience working in a hospital and I feel very good whenever we are able to bring a new drug to the patients. I want them to have the opportunity to receive the best treatment possible.

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