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*Pavla RozmarovÃ¡,*

*clinical research associate manager & regional OD for the Czech affiliate of German CRO Scope International, describes how the Czech clinical research landscape has evolved in the past few years and how Scope has moved to employ a younger generation to capitalize on the industryâ??s technological shift. Moreover, RozmarovÃ¡ shares her views on the local regulatory environment and how the Czech Republic will be able to compete with other countries in Europe.*

**Pavla, what have been your main priorities to build the affiliate over the last few years?**

Scope International has been present in the Czech market for 19 years already, so my recent priorities have been to create a compact team that can implement the new technologies and approaches that are encroaching into the area of clinical research. We increased our team, with a focus on employing young people. The younger generation is familiar with these new technologies, embrace them well and thus can improve Scopeâ??s ability to use them to our advantage in clinical research.

One important decision we made six years ago was to move to a new office, here in Futurama Business Park. Our previous location was nice but was lacking a developed infrastructure. Now, we are more attractive for this younger generation, who want a location to enjoy both work and life, stay connected to what is happening and have good opportunities to meet people somewhere close to the city. We can offer that now, in an environment where people can combine professional and personal or family life.

**Can you give our readers an overview of Scope Internationalâ??s clinical research footprint in the country?**

We are a multinational company, with our head office just over the border in Germany, and locations in almost all important European countries, UK and USA. The Czech affiliate is the third biggest in our group, held jointly with Spain, behind the HQ and that in Lithuania, as they provide medical writing, safety, and data management services for the whole group. Although we are paired with the Slovakian team, our employee numbers comprise of 25 people.

We conduct between ten to 12 multinational trials in the country, across a large range of therapeutic areas. Some indications are focused on innovative areas, where we have had the opportunity to work on Advanced Therapy Medicinal Product (ATMP) studies. For example, together with the Czech investigators, we were the top recruiters of for autologous transplantation of human cartilages, which is a specific trial that is covered under the human tissue and cells laws. It was a challenge, but we were able to develop this know-how and something we at Scope our proud of. We have performed several Phase I trials in this area, focused on monitoring and trial management.

Another success story we can share is in the area of neurology, particularly epileptology, conducting most trials for over 15 years, in addition to trials in all womenâ??s health indications. We are experienced in trials with narcotics and currently we are also running trials with therapeutic cannabis. We have been involved in pain treatment, allergology, pneumology, rheumatology, urology, oncology, otorhinolaryngology, psychiatry and others.

We have been lucky to contribute to the launch of eight 8 new medicinal products in the EU and USA markets which is really exciting and meaningful for us.

**Scope Internationalâ??s focus is on â??cost-effective services, cost & qualityâ?•. How do you execute this in the country?**

Scope offers experience, expertise, and flexibility. Along with a stable team, we are all extremely motivated and involved in all the projects ongoing. To execute this, it is important for us to find strong partners. That means clinical trial sites that will ensure the recruitment of the agreed numbers in a reasonable time and provide professional services. For example, they reliably follow all the procedures and have a professional and responsive team. All these things, in the long run, have a big value. We have a network of sites that we always cooperate with, in addition being experts in their medical area and are able to serve as coordinating investigators. Our relationships are built for the long run. We can address our partners if we need information directly and receive feedback immediately which is important.

Another important way to meet the needs of our customers is through our digital platform KaleidoSCOPE. This was a big step for Scope to embrace such a high-level digital system, but the time and effort is already paying off. All clinical trials run under this system, which offers the

customer direct access to various parts of the database and gives a good overview of the whole running of the trial. This data can be accessed remotely, from anywhere at any time.

**Looking at the Czech clinical research landscape, how have you seen this evolve over the years?**

Everyone in the country has been influenced by new technologies. Study subjects can use their devices equipped with digital applications for clinical trials during the study and know well how to operate them. Unlike in the past, patient diaries can be run like applications on smartphones. Patients and doctors alike are open to these new technologies, as they give a great overview of the data, which the sponsors need as fast as possible for research and business reasons. These applications are very reliable and accessible to all and have changed the overall approach to clinical trials.

Moreover, in the Czech Republic, the regulatory environment and the healthcare system both work in our favour and have been well organized for some time. The latter exploits advantages of a very reasonably planned and developed system of healthcare with a dense network of GPs and outpatient specialists and highly educated and experienced hospital teams, the foundation and development of which goes back to times before the Velvet Revolution. Compared to other countries, we have a very dense network of specialized clinics with high-quality clinical equipment, where all administrative work is completed on advanced service platforms.

**Where would you like to see improvements in the countryâ??s clinical landscape?**

We have relatively old laws or acts regulating the area, which could be updated. However, we expect new regulations to be approved this year. All the key stakeholders, from the government to the industry regulator, the State Institute for Drug Control (SUKL), and members of ACRO and AIFP can influence this clinical research landscape.

In addition, we aim to see updates to the design of clinical trials, where studies aim to be smaller and adaptive, in line with the industry shift to become more personalized for the patient. This should also be reflected in clinical research.

Now, SUKL is trying to be proactive, and react to global changes, and not be so strict on procedures which were significantly different some years ago. They are now more open to discussions, but always approving applications based on good documentation and reasoning.

**How would you assess the Czech Republicâ??s ability to â??Close the Gapâ?• on Europe?**

One of our biggest advantages is our regulatory environment. SUKL is very professional and transparent, who stick to their deadlines. This is a big differentiator from other countries in the CEE Region. SUKL is strict but our sponsors usually respect any appeals from SUKL and see them as rational, as they use a scientific basis for any decision they make.

The Czech Republic has strong potential, and I think that we can influence regulatory authorities in other neighboring countries. The most obvious being Slovakia, as we are closely connected historically. We can share our experiences and somehow help them to improve some of the

procedures in this area.

**In a country with one of the lowest unemployment rates in Europe, how do you continue to build and motivate a strong workforce?**

For the last two years, this has been our main challenge. We are not looking to employ large numbers of people, so we have a very individualized process. The challenge is that there are not enough talented people in the country to feed the needs the of rapidly developing industries, so I have to offer them positions we did not have in the past, for example, more participation in the overall company and management of projects. Previously, these were centralized, however, this means we can now support other offices with our experienced Clinical Research Associates (CRAs) or with training programs and last but not least in project management tasks.

Looking at women in business, the Czech Republic is still a little traditional but changing significantly. As the country continues to become more open, with more and more people traveling, studying and working abroad, learning new languages and generally embracing new cultures, I am optimistic that we will still learn more from the Western World and continue to adapt.

**As Scope International is celebrating its 20th Anniversary in 2020, how have you been celebrating?**

We are proud to say that the Prague office had an opportunity to celebrate in advance. In October 2019, we held our biennial directorâ??s meeting. We were honored to welcome our global directors to our office, making a big effort to impress them with our culture, and our pride in the city, whilst informing them about the advantages of the Czech clinical landscape. It was a big success!

**Finally, where do you hope to take the Czech affiliate in 2020?**

I hope that we will still have room for growth. Already, we know that we will conduct even more clinical trials in the country. Somehow, we are still interesting for sponsors who are actively asking for trials to be conducted here, which is fantastic and paves the way for an exciting year. We are looking forward to taking part in challenging innovations in the clinical trial environment, those currently running and under development.

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