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Csilla LÃ©ka, general manager of Global Clinical Trials in Hungary shares her insights on the portfolio of the company, the most prevalent therapeutic areas, the developments in clinical trials over the last decade, and her outlook on the future of the company.

Can you introduce yourself and Global Clinical Trials (GCT)â??s operations here in the region?

As a general manager Slovakia, Hungary, and the Czech Republic are under my responsibilities. I am originally from Slovakia and can also speak Czech. Before entering into the contract research organization (CRO) sector in 2010, I had been active in quality assurance and sales for the food industry. I started as a CRA, has been working as a project manager for a couple of years, and now also act as the General Manager of these three markets.

GCT is a US company with headquarters in Princeton, New Jersey. With first operations started in 2001 in Russia, thereafter, its growth was focused in the CEE region, with offices opened in Ukraine, Bulgaria, Romania, Hungary, Slovakia, the Czech Republic, Poland and Moldova. The company is a full-service CRO that combines global coverage with local expertise. GCT is an end-to-end service provider in a variety of therapeutic areas, including CNS, gastroenterology, ophthalmology,

oncology, rare diseases, reproductive health for both pharmaceuticals and medical devices.

What attributes make the markets you cover significant for the company?

This region has continuously grown in recent years and become very attractive for sponsors. In comparison with Western European countries, Hungary has large state hospitals, which facilitates the conduct of clinical trials, while patients get access to treatments that are not otherwise readily available.

Were you able to achieve the targets that were set at the beginning of the year?

GCT managed to outperform our targets. The goal was to persuade sponsors to launch new projects in those three countries by meeting the timeline and targets in the ongoing projects. This entailed achieving the recruitment target for patients and providing the quality data

What are the most demanded services from your clients?

Our clients mostly come from the US and vary in size and strategies: we deal with established multinational companies and start-ups. Some biotech companies require full-service starting from medical writing through investigational medical products logistics, courier services, data management and biostatistics support. We build those activities around the needs of the clients to create a bespoke approach.

We work frequently with innovative drug producers and companies that have own R&D department, however, many generic drugs makers are our clients, as well.

Which are the most prevalent therapeutic areas in Hungary?

The main therapeutic areas that GCT is involved in Hungary are ophthalmology and womenâ??s health. This is likely to change as clinical trials have been shifting in focus in the last several years. As a global organization, the therapeutic portfolio that GCT caters to varies from CNS, gastroenterology, oncology, rare diseases, reproductive health and medical devices. The latter, in addition to paediatrics, are areas that are increasingly growing in demand. This is reflective of a global trend but is also prevalent in the three countries that are under my supervision.

What is your approach to new clients who never worked with a CRO beforehand?

These clients require more time and more communication, as the priority to identify the gaps in their knowledge and their capabilities. Once, the relations have been established, GCT is then able to provide a catered service to their needs. Nevertheless, open and honest communication is at the heart of this endeavour and determines the success of any collaboration. Another element to take into consideration is whether the Client is growing or has the team in place, as this will also influence the scope of our services.

What are the major trends impacting clinical trials in the CEE region?

The major trends that affected the clinical trials are the digitalization of various tasks and business/medical processes. This has greatly improved the speed of processing and analysing the data and each step in the clinical trial.

Furthermore, in Hungary, the government has been increasingly supporting clinical trials. For example, the regulatory and ethical committee approval is amongst the fastest in the world. The centralization of state institutions and committees are factors that influence the speed.

What are the key strengths of Hungary, Slovakia, and the Czech Republic in attracting clinical trials?

Regulatory approval timelines are reliable, and this gives security to the sponsors when planning the project. The centralized hospitals and clinics are another factor, as it makes recruitment for trials quite easy. The expertise of the medical practitioners and the research environment are not inferior to Western Europe, which is another key strength.

What are some areas that you think could be improved?

However, GCT is a part of the Hungarian Association of Clinical Trials which deals with contracting sites and this is still a complicated process. There is no standardization in place which renders the process longer than necessary. Furthermore, education about clinical trials is an important area in which Hungarian patients are falling short compared to the rest of Europe. Even though GCT and other players try to dissimulate information regarding new trials, patients are seldom aware of new areas.

How can Hungary and the CEE region remain competitive against the rise in clinical trials in Asia and Russia?

Generally, this is much driven by regulatory aspects. Hungary and most other CEE countries are members of EU that allows Sponsors to conduct clinical trials in one of the most regulated environments, though still experiencing cost-cutting on investigator fees in comparison to leading western European countries. In addition, there are some limitations for international early-stage clinical trials in Russia and Asia that does not exist in CEE region. Again, regulatory approval speed is one of the fastest in the word, which allows us to compete for the studies that require fast start-up.

Do you see the Electronic Health Service Area (EESZT) creating new opportunities and enhancing clinical trials in the country?

As the system centralizes all the data of all Hungarian patients and makes it accessible to health institutions, this will be the go-to tool for clinical investigators when looking for patients. This and other features will be enhanced further with the government push to bring 5G to the country.

How does GCT positions itself as a partner of choice for new clients?

The company has strong business development teams in Russia and the US, that do an amazing job in attracting new clients and creating reliable partnerships.

GCT is a global CRO yet not such a large scale as TOP-5 CROs. Therefore, GCT offers a unique combination of cost competitiveness and personalized approach to each of our clients. We value long-term partnerships, which allow us to build the relationship over time. Furthermore, this creates seamless cooperation as the needs have been identified and the modus operandi has been established previously. For instance, we have been working with one of our clients for more than 10 years. In addition, we are proud of our loyal team that on average stays with us for 5-6 years. There are several exceptional project managers working at GCT for more than 10 years.

GCT has the flexibility to adapt according to the need of the clients at every step of the clinical trial cycle.

What are some of the objectives for this regional cluster?

GCT was originally focused on the development in CEE region due to centralized healthcare system and faster enrolment timelines. Besides, the region offers competitive pricing for study conduct.

The aim would be to continue the regional growth in terms of headcount and number of clinical trials by bringing more Sponsors to this region.

What is your final message on behalf of GCT?

GCT is a great reliable partner for pharmaceutical companies to help develop their drugs and medical devices in win-win manner and by providing full scope CRO services to support their operations. If you are looking for a customized regional, therapeutic and service solution, then GCT is definitely your full-service CRO of choice.

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