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Olga Starobová, medical director of Syneos Health Czech Republic, walks us through the steps put in place to ensure successful synergies during the merger between INC Research and InVentiv Health, which has created a unique company with both clinical and commercial operations under one roof. Starobová talks about her views on the benefits of conducting clinical trials in the country, how trials in rare diseases and gene therapy are the future, and why she is excited to see more of them in the Czech Republic.

Olga, could you start by introducing Syneos Health to our international audience?

Syneos Health was born at the start of 2018 from the merger between INC Research and InVentiv Health, to include one of the top Clinical Research Organization (CRO) in the world and the leading Clinical Commercial Organization (CCO) as one company. We have become a unique company, as the industry's only fully integrated biopharmaceutical solution organization. It is an advantage now to have both research and commercialization operations under one roof. We work "in sync", and this is where "Syn" in our name comes from. The latter part "Neos" has Greek meaning and can be interpreted as meaning "in an innovative way".

As a joint company, we have the capacity to conduct trials from Phase I, or even preclinical, through all the phases until phase IV and Late Stage, and then to commercialization as well. Our main capability or added value services is our unique Biopharmaceutical Acceleration Model (BAM), which is an end-to-end concept, working across our clinical and commercial capabilities and driven by each and every one of our employees.

Moreover, our commercial insights mean that we can play a vital role in clinical trial design. On the one hand, we can develop recruitment practices or strategies, thanks to our commercial data. One the other hand, our deep clinical knowledge can pave the way for multichannel commercial programs. With all these solutions, we can create better, smarter and faster methods of bringing therapies to market. That is why our motto is “shortening the distance from lab to life”.

Speaking of synergies, how did you create these in the Czech Republic?

During the merger, everyone from the global executives to the local teams kept in mind that we needed the “best from both”. This meant taking the best procedures from both organizations. Then, we put them in place and to the test, to do the best work for our customers and stakeholders alike.

From InVentiv, among the others, we brought the best commercial data and insights. From INC Research, for example, we took The Trusted Process, which is our metrics-driven methodology to manage all aspects of clinical trials. This is one of our key differentiators, a unique, four-step approach, that delivers faster results whilst maintaining data integrity and reducing operational risk. These are just examples, but concrete evidence of how we have brought both companies together during the merger.

Can you give an overview of Syneos Health’s footprint and clinical operations within the Czech Republic?

In the Czech Republic, we currently have 124 employees, with a near-equal split between those based in the office and at home. Currently, we are running around 149 clinical trials, with some in their starting phase and others in the maintenance phase. These trials are conducted in about 454 sites in the country, and for 81 different customers. This means that Syneos Health is present in around 35 percent of all clinical trials ongoing in the Czech Republic, which is a fantastic number.

Our main therapeutic areas for research are split into three business units: CNS, Oncology, and General Medicine. CNS covers a variety of diseases, including psychiatry, neurology and rare diseases. Oncology is, of course, a very much growing therapeutic area. Finally, General Medicine covers areas like infectious diseases, rheumatoid diseases, and ophthalmology to name a few.

Our key differentiator compared to our competitors is that we are therapeutically aligned. Meaning, all our associates and employees have deep knowledge or experience in one of these therapeutic areas. This gives added value to the sponsor, as the trials are managed by experts in the therapeutic area.

Syneos Health's goal is about "shortening the distance from lab to life". What does this mean and how do you execute this in the country?

This means that we take all of the knowledge we have, from clinical trials conducted in early phase to those in their final stages, along with our commercial insights, and put this know-how together to influence how we bring a product to the market. Our focus is always to shorten the time of access for patients.

How would you compare the Czech Republic's clinical research landscape to the CEE Region?

The Czech Republic is a small country, with ten million citizens. However, we have ten medical faculties in six different universities across the country. This means we are extremely capable of producing experienced medical doctors. The contemporary problem, which many countries are facing, though, is that some doctors are leaving for employment abroad.

Nevertheless, in terms of clinical trials, we have very knowledgeable sites, and they all have a deep understanding of Good Clinical Practices provided by the International Conference on Harmonization (ICH-GCP). Some even have their own standard operating procedures, for example looking at informed consent process or on reporting of adverse events and so on.

In this country, we have a running Universal Healthcare System, where all patients are covered by health insurance companies. This means we have a big patient pool to conduct clinical trials with. The healthcare system ensures there are many different medical facilities, e.g. hospitals, clinics and private sites, varying in size, along with very specialized centers. This for example includes the

Institute of Clinical and Experimental Medicine (IKEM) in Prague and the Masaryk Memorial Cancer Institute (MMCI) in Brno, in addition to other university hospitals joined to medical schools. They all are the best in the country and provide the best in class treatment. Therefore, from a clinical trials perspective, we have a bunch of sites to choose from, and some of them even best in the region.

These sites are reliable, and they are also good at recruitment. They can capitalize on this big patient pool and produce quality and reliable data, which is always important for any clinical trial.

As the number of clinical trials in the country continues to decrease, what do you think could be done to turn this trend around?

Our regulatory body, the State Institute for Drug Control (SUKL), can be perceived as strict when assessing clinical trial applications. However, I have experienced how this works with them. Of course, they have requirements on what should be changed in the protocol. My own experience involved medical writing. We submitted a protocol in different European countries, mainly in the CEE Region. SUKL came back with their special requirements on country specific protocol amendment and the sponsor was very flexible as they wanted to run the trial in the country. Thus, they agreed to the proposed changes by SUKL.

To breakdown the timelines, we received requirements from SUKL one day, and I was able to adjust the protocol two days later and to immediately sent it back to SUKL. Then it took no longer than three or four days for them to approve it and allow the trial to go ahead in the country. Yes, you could say they are strict but extremely cooperative, fast, and direct in their decisions.

Maybe the number of clinical trials in the country is declining, but we have here high-quality trials where safety is the priority. SUKL and Syneos Health put the patient’s safety at the centre of everything we do.

Concerning the price pressures, I would not say that the Czech Republic is expensive. This is a small market, and for niche indications, we have few specialized centres. However, I do not see this as a big influencer in sponsors deciding on whether to invest their research in the country.

In the future, I would like to see more gene therapies being conducted in the country. This is the future of research and treatment. These types of trials are already ongoing in the country, which is a sign that we are being requested as a site for these trials.

Lastly, Prague is a fantastic location, and great for sponsors to host events. Many investigators enjoy their time in the city when coming here for meetings.

Looking forward, what therapeutic areas will Syneos Health continue to work in?

I am particularly involved in CNS; this is my specialty area of expertise. I think that there is a future for innovative medicines in the Czech Republic, and Syneos Health specifically will be focusing on rare diseases. This is a field where there are many unmet needs. Currently, there is a growing number of small biotech companies developing treatments in this area. An exciting trend that we will be keen to involve ourselves in are clinical trials in gene therapy. There are already two gene therapy treatments that have been approved and brought to the market which Syneos Health has been involved in. The next in line might be perhaps haemophilia A, a rare genetic bleeding disorder; an inherited disease that impairs quite a number of patients.

We are looking forward to working with companies of all sizes, that we can mould our BAM business model well too.

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