Anders Millerhovf â?? CEO, CTC Clinical Trial Consultants, Sweden

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In a fast-changing Nordic CRO industry, CTC Clinical Trial Consultants has opted to differentiate with a unique one-stop-shop approach. CEO Anders Millerhovf reveals how the relatively young company has managed to take over the Swedish scene. Moreover, he outlines the challenges faced by early clinical development and discusses the strategies CTC has established to deal with these challenges.

You are not only CEO, but also one of the founders of CTC. Can you talk about your entrepreneurial journey with CTC since its foundation in 2011?

The idea to start our company originated when my previous employer, Berzelius Clinical Research Center (BCRC), closed their business after ten years of working with early phase clinical trials. We were many who considered it a pity that ten years of experience with phase I trials and well-established working procedures would just become lost. CTC started up in a small office in LinkÃ¶ping. When also Quintiles closed their phase I unit in Uppsala in January 2012, we took over their clinic at the Uppsala University Hospital and our business kicked off for real. I began as Director Project Management, but in fact, I was an all-round handyman with the responsibility for building the company. I called every contact I had in the Life Science area, and one day happened to stumble into a former colleague on the train. He needed to conduct a functional food study, and this became

CTCâ??s first trial in Uppsala.

Because most of the company founders have experience with clinical study conduct, we built the company from a clinical perspective. As we got in more studies, we took in other areas of expertise and customised our business towards phase 0-IIa studies.

How did it happen that you dared to start a new company exactly when two others were forced to close their business?

When in principle all phase I units in the country were closed, half of all clinical trial activities in Sweden disappeared. Early phase clinical trials could then only be executed in hospitals. By starting from scratch with a completely new company, we had the opportunity to adapt the size of the company to the needs of the market. Many people in the industry were worried about what would happen if all phase I studies disappeared from Sweden, and in retrospect, I have realized how fundamentally important it was to keep clinical trial expertise within the country.

What have been your main achievements in the leading role so far?

Over the past five years, we increased the turnover by 200% and grown into a company with more than 60 employees. We have created an effective organizational structure that we can build on by recruiting more people and more expertise. And above all, we have outlined our companyâ??s core values and created a clear framework to relate to. We managed to involve all employees in the process of defining these values, which makes it easier for all of us to identify ourselves with them and use them for guidance. If we now take a decision that fits within this framework, we can feel assured that the decision is a good decision.

I am also very satisfied with our quality management system that is specially adapted to the needs of our services. Our quality management system is the basis of our practical daily work and enhances our efficiency, which is something that anyone in this industry can appreciate. I am proud of the fact that we strive to become one of the most attractive working places in Sweden. Being consultants, our strength lies in our people.

What are the main services offered by CTC to the pharma industry?

CTC offers a true full-service package. We are one of few CROs that conduct clinical trials in our own research units, with our own physicians, nurses, pharmacists and laboratory staff. We also have three other departments full of expertise; Clinical Operations, which comprises project management, monitoring, medical writing and clinical trial administration, Pharmacovigilance and Biometrics including data management, statistics and pharmacokinetics. Having our own experts in-house is particularly important in early phases when itâ??s crucial to meet tight timelines.

Last summer, our holding company Center for Translational Research (CTR) started a regulatory company, RegSmart Life Science. This means that we also can offer regulatory support to our customers both prior to study start and during the conduct of the study. The latest news is that CTR recently acquired the bioanalysis unit of Recipharm, which will continue under the name Lablytica. Our already well-established collaborations will now operate even more efficiently.

How does having your own clinics translate to better results for your clients and the patients?

The whole Clinical Operations team can work closer to the clinic. When we, for example, write a protocol, we receive input directly from our clinic staff both in terms of logistics and safety aspects. We believe that the largest part of the clinical trial budget should be used for clinical conduct. It is when we run the study that we receive our data, and no mistakes are allowed. If we are to call ourselves experts on clinical trials, we need to be able to fully execute the trial and for that, we need the absolute most critical part: the clinics. Moreover, a major advantage for our customers is that they can get everything in the same quote, instead of subcontracting different parts from different vendors.

Can you explain your partnership with Recipharm and the first-in-human â??Pathway to Clinicâ?• service?

Through our partnership with Recipharm, and together with our collaborator Lablytica, we offer our clients support with manufacturing, cost-effective expert advice, bioanalysis, and regulatory support. The service takes projects from the early stages of drug formulation development all the way to execution of clinical trials in patients. We help companies of all sizes â?? from small local firms to big pharma â?? to quickly generate data and increase the value of their compound. The aim of the Â¨Pathway to ClinicÂ¨ concept is to provide our customers with a single quote for the entire process including GMP manufacturing, bioanalysis, and clinical trial conduct from the first-in-human study to Phase IIa.

What is the difficulty presented by working with first-in-human trials?

The challenge is to remain vigilant and adaptive, as the timelines are constantly changing. Many things need to be in place when planning a phase I study, and there are often delays. Sometimes new data appear very close to the study start and completely change the planning. Also, manufacturing problems or unexpected demands from authorities can delay the study. When a first-in-human study has started and the first data are coming in, those data can determine how the study should be continued. This is why we want to get into contact with our customers as early as possible to identify possible risks, make sure we have a plan B and together with the customer set up a well-thought-through clinical program that is feasible to execute. Some things, however, are impossible to predict, and then itâ??s just a matter of being flexible. That is the nature of working with early clinical development.

What collaborations or partnerships do you have besides Recipharm?

In addition to the tight collaborations with our two sister companies, RegSmart and Lablytica, we also have established collaborations with for example ERT, a global data and technology company that offers various technical and software solutions focusing on minimising risk and uncertainty in clinical trials. Together, we apply a special technique called Expert Precision QT (EPQT) as an integrated part of our clinical trials. This technique offers our customers the possibility to collect important QT data at a very early stage, which, in turn, might qualify for a TQT waiver and huge cost savings.

We also collaborate closely with Immuneed that shares premises with us. Together we have created the â??The preclinical human modelâ?• concept through which we offer a unique solution for the preclinical and clinical characterisation of a candidate drug. The preclinical data generated can, for example, be used to determine the starting dose and dose escalation steps in the upcoming clinical trial and to understand the mechanism of action of the drug. In addition, we can mitigate the risk that subjects participating in clinical studies develop immunity against the drug under investigation. This saves time and resources and, most importantly, it increases the safety of the trial.

Dagens Industri has recognized CTC as a â??Gazelle Companyâ?? on more than one occasion, meaning that CTC is one of the fastest-growing businesses in the country. Can you explain your unique growth and how you have achieved it?

First of all, we have many satisfied customers. That creates more work. Secondly, we have gathered a number of experts with long experience of clinical trials to be able to offer a high quality, full-service package. We take pride in our work and are committed to taking on challenges with a positive mindset. The infrastructure in our industry in Sweden is well-established, so we have all we need to grow.

How do you compete with big multinational CROs to attract international clients?

Our customers find us through our personal networks, but also through our website. We work hard to keep our Scandinavian customers, but we also reach out to international clients. We do not want to compare ourselves with large CROs, but if we were to compete and win over them, it would be because we reply quickly, have short lead times and offer expert advice already at the first meeting. Everybody involved in business development at CTC also works operationally and hence has hands-on experience and a deep understanding of whatâ??s required to deliver a study with high customer satisfaction.

What are the main trends, opportunities, and challenges in the Swedish CRO industry?

We see virtual studies, studies executed via the web, as a coming trend. Sweden is a country that has come a long way with regard to digital development, and the majority of the Swedish population has access to an online ID verification tool called Bank-ID. Virtual studies are a logical next step.

Another opportunity lies in the trend that protocols are becoming more and more complex and involve more and more aspects. Combined adaptive designs and the application of complex techniques to collect data are exactly what we are good at! Our challenge, however, lies in the fact that we cannot perform large studies on patients with complex indications because the Scandinavian population is too small.

Looking towards the future, what is your strategy to maintain CTCâ??s growth and continue being that Gazelle company?

We will continue to deliver with high quality, be innovative and agile. We continuously work on optimising our processes and on maintaining our staff and expertise by trying to become the most attractive working place in Sweden. We also want to become more visible throughout Europe so that

more clients come to us in Sweden to conduct clinical trials.

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