

Profile: Clinical Contract Research Organization

TFS Trial Form Support International Lund, Sweden

An interview with Daniel Spasic, chief executive officer

What is Trial Form Support's background?

I founded Trial Form Support [TFS] in Lund, which is a thousand-year-old city in Sweden and one of the oldest universities in Scandinavia. Scandinavia at that time was not a mature market for CROs and I saw the need for them during my time at Pharmacia & Upjohn, where I worked mainly in oncology and CNS [central nervous system]. We had great pressure on us to deliver quite a number of clinical trials, but we had difficulties in coping because our organization was too small. So we started to look for vendors in the region that were a certain size and a certain kind of infrastructure to handle our outsourcing needs. At that time there was only one established vendor and an upcoming vendor that met our criteria and they had a lot to do. So even though we turned to them with a quite attractive program, they couldn't fit it into their schedule. After I'd been working for Pharmacia & Upjohn, both in Lund in CNS and then in Milan, Italy, in oncology, I came back to Sweden where I was recruited by a CRO called Clinical Data Care. I worked there for two years and then I saw the CRO boom at that time, so I decided in 1996 to try the CRO model on my own. Basically we started out with a Swedish operation and then we saw that the market was growing. We grew very fast in Sweden. Our second affiliate was in Denmark. Our third was in Finland and our fourth in Norway. Then in the early 2000s, we were one of the market leaders in Scandinavia. Starting in 2001, we moved out into Europe. We started out with regulatory project

management and monitoring, so we were very much focused in the clinical operation area. Then later on we added data management and statistics. Today we have all the services in-house.

What differentiates TFS from other pan-European CROs?

If you look at private companies, we are definitely the largest CRO in Europe with a European origin. About 75% of the clinical trials we did in 2006 were in phases I, IIa, IIb and III, and 15% were in phase IV, and the remaining 10% were mainly medical device studies. It's our strategy to conduct fewer post-marketing trials at TFS. We want to be quite strongly positioned in early phase. The typical TFS trial today is conducted in between five to 15 European countries and enrolls between 150 and 450 patients with a duration of 12 to 24 months. These trials are a size that fits TFS very well. A differentiator between TFS and many other CROs is that we are a bit selective in the studies we do. We ask ourselves, 'Is this a study size we could cope with? Are these deliverables that we could deliver on?' Then we come back to the customer and say, 'Yes, we can do this study, but we want you to know that it will take this amount of time, and this country might be a challenge to us because we have never done studies there before.' We are very transparent in our communication. I think that has gained a lot of trust throughout the years and there's never a surprise when working with TFS. And if there is a sur-

Year founded: 1996
Employees: 350
Countries work in: 14
2006 revenue: 30 million euros
2009 projected revenue: 55 million euros
2006 ongoing clinical study protocols: 371
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prise, we have in most cases often told the customer beforehand that this could be a challenge.

Another big differentiator between TFS and other CROs in terms of early development is that we have become the market leader in Europe today in early drug discovery when it comes to phase 0 studies and phase I studies where you want to use microdosing and trace the product with PETs [positron emission tomography.] This is what the TFS Early Development Team is very much recognized for. We are doing about eight to 10 PET studies per year. Our phase I facility is located at the Karolinska University Hospital and we have access to several PET cameras about 40 to 50 meters away from our unit, so the logistics are very suitable for imaging studies. A new PET facility in Barcelona, Spain, was added to our infrastructure in late 2006. That's a big differentiator in phase I and phase 0.

What challenges do you face?

The challenges we face are factors outside TFS control such as the decentralized European regulatory environment. I am impressed at how quickly Europe



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can handle the regulatory submission even though you need to apply to different countries, but I would like to see much more centralization at EMEA [European Medicines Agency], making the EMEA something like the U.S. FDA [Food and Drug Administration].

In terms of contract research, one of the challenges is declining productivity in Western Europe, while Central and Eastern Europe are keeping a very steady and satisfying pace in terms of productivity. Western Europe must create an environment within academia that prioritizes clinical research. Each hospital should have a research unit or at least a high priority for clinical research. They should make investigators available to spare some of their time for research and create study nurse teams that are dedicated to research. We only see that prioritization in the major university hospitals, and their problem is that they are extremely crowded with studies. Everybody wants to go to a hospital where there is an infrastructure for clinical trials. This is an infrastructure that needs to be adopted by many more hospitals in Europe.

How has clinical trial conduct changed since you founded TFS?

During the presentation of the [European Clinical Trials] Directive, many EU member states as well as many research companies and CROs were very negative. But I think after working with the directive now for almost three years, you can see that it is really a benefit for Europe because it's harmonizing the countries. There's still a lot to do in terms of really being harmonized, but at least the directive tells you how you should do it, how you should submit your application and when you can expect a response

from the authorities. Previously you didn't have that. So you could start up trials in a lot of countries, and by the time you were ending the trial you got the authority approval in Italy. Today it's more harmonized, and you can predict your timelines much better. So I think that the European directive has been a great competitive edge to Europe. Then it's up to each country to use that competitive edge.

What I think is the biggest change in drug research from 1996 to 2007 is that clinical trials are more closely scrutinized by the companies that sponsor them. They are not only looking for quantities of trials, they are very much looking at the quality of the trials. They are asking themselves, 'Why are we doing this trial? What kind of medical benefit will it add to the community? What is the degree of innovation in this trial and in this product?' It's a much more innovation-driven market today than it was in the early or mid 1990s. One of the reasons for that is that the European regulatory authorities in Europe have become much stricter on me-too products or approving protocols without a clear benefit for the patients. And as generics are coming into the business, the pharmas have realized that they must have innovation in order to gain future revenues. So innovation and the quality of the clinical trials that are being approved today internally by companies have increased significantly since the early to mid 1990s.

Do you get trials from Indian pharmaceutical companies?

We have a sales office in Mumbai, but we don't do any operations in India. The sales office is working hard to bring Indian companies and their clinical research to Europe. We are actually starting our first phase I trial with an Indian company in the area of

diabetes. We have two more trials scheduled for the first quarter of 2008, one in oncology and one in cardiology, that will be sponsored by Indian pharma that want to conduct those trials in Europe. We also have a sales office in Tokyo. In 2006 about 13% of our total revenue came from the Japanese market. We talked a long time about doing the same concept in the U.S., but we sensed that an acquisition opportunity would be a much more attractive solution for us.

What are your plans for growth?

The growth in the coming years will be a combination of acquisition and organic growth. We have a corporate target by 2009 to grow an additional six European countries. In 2009 we want to be positioned in 20 key markets in Europe and bring the revenue up to 55 million euros. Right now we are in the middle of a due diligence process with an East Coast CRO in the U.S. that we have partnered with for seven years. We are running seven clinical studies in the U.S. for European customers through that partner, and we are running 12 clinical studies initiated by U.S. biotech in Europe through that partner. We always find ourselves in a position where we need to defend the partnership. When a U.S. biotech wants to do trials in Europe, and when we conduct trials in the U.S. for European customers, they have the same questions—'Can we rely on your partner? How do you control their processes? How do you make sure that they are doing the study according to your quality systems?' We believe that we will create significantly higher confidence in working with us when we can say, 'Yes, we have representation in the U.S. It's the same company, it's the same ownership, it's the same systems, the same SOPs' and so on.

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