Interview: Denis Comet â?? President of AFCRO (the French Association of CROs) and Axonal-Biostatem, France

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The President of Franceâ??s Association for CROs (AFCROs) discusses the issues surrounding Franceâ??s clinical research sector and the actions that both the public and private sector need to take to maintain their competitiveness. He also discusses his companyâ??s recent merger with

Biostatem and their mission to internationalize.

While France remains an attractive country for clinical trials, both LEEM and AFCROs have warned against the decline of the clinical research sector in France. How difficult do you think it will be for France to maintain its position within the now very competitive international clinical research market?

France still possesses three significant advantages in the clinical research field. Firstly, we have an extremely well-organized, centralized and interlinked research and medical network, especially in key therapeutic fields like oncology, infectious diseases (e.g. AIDS) and neurology, for instance, through organisations like INCA (the French National Cancer Institute). Secondly, we have universal and efficient healthcare infrastructure, in terms of both personnel and systems, which means that it is easy to get a representative sample of the (diseased) population, even in smaller cities and towns, not just Paris. This is crucial for clinical research because it prevents biased or inaccurate data with regards to healthcare coverage by medical practitioners. A lot of research happens in places where it is easy to find patients, but this ultimately gives biased findings. When a company wants to launch their drug in Western markets, the relevant authorities *(FDA, EMA)* may question why 90 percent of the clinical trial participants are from China, Russia and Brazil, but the drug is marketed at Europeans. They may ask for a new phase III, which would mean the first attempt was lost. Finally, our doctors are not only excellent medical practitioners, but also good scientists and technicians, which means it is easy to work with them on medical research. These are our strengths, and I think they are very compelling arguments for France as a clinical research destination.

As the President of AFCROs, what are the key steps you would like to see the authorities take to ensure France remains competitive in this sector?

It is crucial for the French government to implement measures to reduce the administrative and regulatory delays in the clinical research process. Currently, there are many biotech companies who do not conduct phase I-II trials in France because the process is such that you can finish in other countries before you can even start in France. Speed is critical for biotechs because they need to show concrete results in order to get additional funding for the next period.

We are no longer competing with developing countries like China and Russia as they catch up. We are behind even our European neighbours in some aspects. For instance, in 2012, we pioneered clinical research laws (through the *JardÃ© Law* aimed at regulating research on human beings); including lot of substantial improvement for the clinical research, but due to delayed passage through the national assembly, the EU has now come up with its own set of laws â?? which are based on ours. The French government is now waiting for the EU legislation to come out in 2016. We have gone from being the regional leader to a follower. Another example of how administrative and regulative delay can erode our competitiveness is about the Standard contract. A similar initiative has already been active for two to three years in the UK even though they developed their clinical research sectors later than France. In Germany, the clinical research authorisation process can be done in seven days but in France, it can take up to six months.

The government has already implemented some policies that will benefit the clinical research sector. For instance, a standard clinical trial agreement, known as the Standard, has been created, which will simplify the negotiations of the contractual relationships between the sponsor, the investigator and the healthcare centers involved in the clinical research.

But only 50 percent of the work has been done and the government needs to continue its reforms. We are competitive on the authorization of clinical trials, but there are other regulatory aspects of

clinical research: site selection, site contracting and participant recruitment, amongst others. For instance, the time for site contracting can be reduced to one month if a similar standard contract was introduced as a compulsory template.

What role can the private sector play in helping France to maintain its competitiveness in the clinical research sector?

An important aspect of clinical research is patient recruitment. Sociologically, the US is the EUâ??s major competitor in clinical research because of its healthcare system. In the US, you have to pay for your drugs, and sometimes the cheapest access to new drugs is through clinical trials. This encourages people to sign up for clinical trials. The same is true in Eastern European countries. Franceâ??s universal free healthcare system is unlikely to change. The solution is to create the right kind of positive publicity for clinical research. It is crucial that we change the image of the pharmaceutical industry. In France, there is a lower level of public confidence in the pharmaceutical industry than in the tobacco industry! Nobody talks about the successful clinical trials, only the failed or controversial ones. But many lives are saved in these trials, especially in cases where conventional drugs have failed and the experimental drug being tested was the patientâ??s last hope. We need to hear about stories like this in the media. This is a case where we have excellent regulation: the Temporary Authorisations for Use (ATU), which allows for the compassionate use of experimental drugs under certain circumstances. This both facilitates clinical research and saves lives.

Letâ??s now move on to the company you founded in 1989, Axonal. In May 2015, it was announced that Axonal and Biostatem would merge to form a leading European CRO. Why was Biostatem the right partner for Axonal?

Our M&A strategy is a happy medium between the â??affiliatesâ?? model done by international CROs and simply subcontracting. We understand that the success of any partnership comes with the right partner and maintaining the right sort of relationship with them. We therefore meet with partner companies and align key areas like quality assurance and IT. Then we also leave a representative of Axonal at the HQ of the partner company, to ensure good communication.

The recent merger with Biostatem is geared towards internationalization: we want to have the scale to operate at the international level. But at the same time, we need to make sure we partner with a company that is a good fit. Biostatem was a good fit because of their small size and their expertise in epidemiology and vaccines, which complements Axonal very well. We would like to partner with companies that are of similar size to Axonal, have similar aims of international expansion and significant expertise in particular, niche areas.

Today, Axonal-Biostatem have offices in London, Prague, Budapest and Warsaw with operations in many more countries. How important is international development as a pillar of growth for your company?

As I mentioned, the core of my current mission is to internationalize. It started five years ago when Sanofi was then the top pharmaceutical company in the world, and my thinking was, if a French pharma company can become the best globally, so can a French CRO! At the same time, I was also seeing increased competition from foreign players in the French market, and I knew French companies had to do the same and expand internationally. At the start, I knew I needed capital if I were to compete internationally, and so I sold a part of my company to Banque Publique dâ??Investissement (BPI) as it focuses on supporting SMEs and innovative enterprises in support of public policies.

I have stated that I want to achieve EUR 10 million (USD 11.2) revenues by 2020. Axonalâ??s current turnover is around EUR 4 million (USD 4.49), but as a group, including Biostatem and Acuitude, we have a turnover of nearly EUR 8 million (USD8.98), so it is not as ambitious a target as it may seem. Tentatively, I would say, we would like 40 percent of that revenue to come from international markets. We set up five studies last year. One of them was 90 percent based outside of France. We are making good progress with our internationalization strategy.

How would you define your comparative advantages versus much larger CRO players and what is your specific edge?

There are essentially two business models for CROs. The first one, focused on Phase II/III, has already been conquered by big international CROs, because you need a large global company to manage these large-scale studies. The second model is what we are doing. We focus on the late-stage, post-registration local studies, such as data collection, market research, and implementation. These are areas where you need up-to-date, very local data for specific regions and countries of interest. Big companies cannot be good in these areas because you need localized expertise and that is not their core business. At the start, we needed to convince the big international companies to work with us. We had to convince them that we were a better fit for some areas of clinical research than the big established companies, and in that way, we carved out a niche in the international real-world studies.

Axonal-Biostatem prides itself on the stability of its senior management and low overall staff turnover. What factors do you think account for this?

Fundamentally, this is more than just financial benefitsâ?¦ Our unique selling point is that we combine the intimate environment of a small company with the opportunities to do very interesting work with the international aspirations and experience of a big company. We strike a nice balance between the two, and I think that is what makes us such an attractive company to work for.

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