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*A senior director for Icon plc discusses Argentina's strengths and weaknesses as a venue for clinical trials, the role the market plays in a global clinical trial strategy, and Icon's ambitions for growth in the region.*

**What are Argentina's strategic advantages in terms of clinical trial strategy?**

Argentina in general has a strong record of doing high quality work relative to other parts of Latin America. If you look at the development of clinical research in Latin America, Argentina has always been a leader. As such, the market is significantly more evolved here in the sense that there are more sites that have been developed specifically for clinical research, a good supply of well trained and experienced staff, as well as the proper processes and infrastructure in place. Another aspect is the size and accessibility of patient populations, which can be recruited effectively through the public health system, and the level of regulatory oversight and inspections has always assured that trials are conducted properly and safely.

**Would you agree that approval timelines and import restrictions are significant barriers to the success of the Argentinian CRO industry?**

Yes, the key challenge for us in Argentina is the start-up timeline, as the trials will start later in Argentina than in other countries. We cannot contribute much to preliminary or early results because of this, as the timelines have become increasingly predictable, they can now be worked into a clinical trial plan effectively. Also, there is currently an initiative underway between ANMAT and the industry to develop and launch an electronic submission system; I've heard it's supposed to be launched sometime next year, and hopefully it would help to reduce these delays considerably.

As far as import challenges go, I think the CRO industry has a relatively easy time of it since we bring so many dollars into Argentina through invisible exports. We've had the odd issue here and there, but it hasn't been a general challenge like it is for many companies.

**Are there any other issues you feel are constraining the industry?**

Another complexity we have as a federated country is the fragmented and inconsistent healthcare regulations, as studies are regulated at the provincial level as well as the national level. This makes for a bit of an administrative burden in terms of application processes and paperwork. However, there have been some recent national initiatives to harmonize the different provincial systems with respect to a variety of issues including clinical trial registrations and regulations, so the situation has improved considerably in the last three years.

**How does this slow approval process affect the types of studies you are choose/are able to bring to Argentina?**

For studies that are able to recruit relatively quickly globally, and that doesn't need to last a particularly long time, Argentina isn't able to contribute much; by the time we would get the necessary approvals in Argentina, we would already have recruited an adequate population elsewhere. Colombia has the quickest approval times in Latin America (and used have by far the fastest "start up times" until they recently introduced new rules requiring separate approvals for each site opened), followed by Chile, Mexico and then Brazil and Argentina.

**Other CRO managers have suggested that physicians in Argentina have better relationships with their patients than in other countries. Do you agree and how does this impact clinical trials?**

It is true; I would say that in general Argentinian's have closer relationships with their doctors than patients in other countries. This extends to the study team of investigators and nurses that a clinical trial patient interacts with as well. I think this is probably promotes better patient retention,

which is another strength of Argentina; in general, clinical trial patients stay enrolled longer on average than in other countries.

For longer-term studies, having higher patient retention rates is particularly valuable as you are able to succeed with a smaller initial population if the attrition rates are lower. Also, having patients enrolled for longer gives you better safety data, and a better picture of the long-term consequences of a drug. Argentina is a strong participant in such studies; for instance, we have a long-term global cardiovascular outcome study, and Argentina is one of the top enrollers. Latin America as a whole contributes roughly 20 percent of the patients worldwide, say 3000 out of 15000, and 1500 of those patients are Argentinian.

**At which types of clinical research is Argentina most competitive?**

If you look at the statistics from ANMAT and CAOIC, it’s quite clear that Argentina is only really active in Phase II and Phase III trials, and Phase III would be the largest. As far as what sort of studies we bring here, as we’ve already discussed the importance of approval, recruitment and enrolment timelines, and in general studies with longer timelines are better suited to Argentina. In this regard, Argentina fits in as a location to go to once other countries have reached their “plateau” to find bulk populations, or to recruit long lasting populations.

At the moment, there is a lot of oncology research in Argentina, so you could say Argentina is competitive in oncology. This prevalence of oncology is partially because we have good research infrastructure and a reasonably large population, but a big factor is that many oncology studies follow patients for very long periods of time, and it is difficult to find patients for many of these studies, as they must have a particular gene. As I mentioned earlier Argentina has very high patient retention rates and average enrolment periods, and our slow approval timelines are less of an issue when the recruitment process is also relatively slow.

**Is there much interaction between the global CROs and local companies and CROs?**

In general, the local companies work with the local CROs for their clinical trial needs. The Argentinian biotech sector, and pharmaceutical industry itself, are becoming increasingly innovative and a few are working on bringing biosimilar (or incrementally innovative) products to the US and EU which requires clinical testing of the products, so we are interested in seeing what happens in the future with respect to local demand for trials. We recently had a Brazilian company approach us that was working on getting a product certified with the FDA, and they wanted the support of a global CRO; perhaps we will see something similar here sometime soon.

**Now, moving onto Icon plc specifically, could you tell us a bit about the Argentinian office's role within the global organization?**

The Buenos Aires office was opened in 1998 and was the first for Icon in Latin America. Starting in 2004, we started expanding into the region by opening office in Mexico and Brazil, then Chile and Peru in 2005, and Colombia in 2007. Today we have about 430 employees in Latin America, out of 11 000 for Icon globally, so we are still very small relatively speaking. At the global level, Latin America is still a primary target location for further expansion.

Icon has also opened an office for our staffing and HR division, which is called DOCS, in 2007 and they now have more than 100 people in Latin America. I think this division will grow in the region rather quickly, outstripping the clinical trial business. We may also see some more growth in our commercialization and outcomes business in the coming years.

The key issue is that as of yet Latin America is not generating a significant number of clinical trials, so the affiliates here focus primarily on project delivery and not the commercial side. If and when the pharma industry in the region starts contributing more to life science innovation, we would restructure to better reflect the needs of the market.

**Globally, Icon is known as having particular strength in cardiovascular, oncology, biosimilars and a few other areas; which of these strengths are most apparent in Argentina?**

We've had projects in cardiovascular and oncology projects for many years and have recently seen an uptick in biosimilars; our business here is representative of the global business. Aside from that, we have a lot of work on rheumatology at the moment.

**There are a lot of capable multinational CROs; why should Icon be the partner of choice?**

Our corporate vision for Icon at the moment is to be the trusted partner, and there have been many efforts to reinforce our reliability and ability to support our customers unique needs. One of these initiatives is the development of a consulting group, so we will be better able to provide professional advice regarding issues of clinical development and commercialization.

**Since Focus Reports interviewed you last time in 2009, I understand that your position has changed substantially?**

Yes, there were a number of changes made within Icon to better adapt to the market. I was made a clinical strategist for a while during this transition, and was working closely with the cost proposal

team to determining the best approach for a particular opportunity, where to place the clinical trials, and delivering a final proposition to our clients.

That only lasted for two years, and now I am a senior director for clinical trial management. It is my responsibility to supervise a number of clinical trial managers in Latin America and the U.S., at the moment I have 17 such managers reporting directly to me from Argentina, Brazil, Colombia, Chile, Mexico and the U.S.. At the moment, all of them are working for our main client, Pfizer, as can be expected following the strategic alliance Icon made with Pfizer in 2011. I also wear another hat, and that is as the site head for our office here in Buenos Aires.

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