

Pivotal Madrid and Barcelona, Spain

An interview with Ibrahim Farr, MD, PhD, chief executive officer

How and why was Pivotal founded?

I had been involved in global clinical research at multinational biopharmaceutical companies as head of CNS clinical research in Europe and also as a regional senior medical director. Based on my experience of more than 20 years on the international and local levels, I thought there was an opportunity for a new CRO model, one with a fully fledged medical department as they have in a pharmaceutical company. I had the vision for a regional CRO, whose medical department would offer a strategic function, not just a tactical function. Tactical services can be provided by any CRO; however, giving good strategic input, apart from implementing the trial, is something that, as medical director at various companies, I found lacking from the services that CROs in Spain and Portugal—both multinational and local—were providing. So, with that in mind, I set up Pivotal as a company with three clearly integrated divisions. One is dedicated to medical affairs with seven medically qualified physicians, four of whom are working full-time for Pivotal and three part-time. Around that heart of the company, there is the clinical research tactical organization with more than 60 people working as project managers and lead CRAs, senior CRAs and CRAs. The third division is the data management/biostatistics division, which is staffed by more than 25 people. That vision for establishing a strong strategically driven medical department with a therapeutic focus across all functions—medical

department, clinical operations, as well as data management and biostatistics has been a success.

What differentiates Pivotal from other CROs in Spain?

There are three clear differentiators. One is that we have physicians on board who are dedicated to not only act as project managers, which other CROs have, but they are the thinkers. They can sit down together with the operational team and think about our clients' protocols, brainstorm on design, and offer input about the therapeutic area. This is an added value not only for the client but also internally because they advise our clinical operations personnel as well as the data managers and biostatisticians regarding that therapeutic area and they train them on how to analyze and input certain interpretations of the therapeutic area. This is definitely a feature which is not found in other CROs in Spain and Portugal. Other CROs have M.D.s on board but they are dedicated to tactical issues, to being project managers. At the level of multinational CROs in Spain, they do have that function but it is located outside Spain, in their head office. Having a fully fledged medical department which is strategically oriented to support clients as well as the internal tactical functions of the company is a major differentiator for Pivotal.

The second differentiator is our therapeutic focus. Although we serve clients in all therapeutic areas, we

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Employees: 100
Active projects: 73
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do have a focus in a few. We are proud of our specializations, one of which is onco-hematology. We have positioned ourselves in Spain and Portugal as a reference company in this area. About 40% of our business comes from onco-hematology. Within cardiovascular, we have significant expertise in acute coronary syndrome as well as some in the medical device area such as pacemakers. The acute cardiovascular area is more specialized and hospital-based and includes emergency and coronary care patients, rather than the chronic cardiovascular area, which includes hypertension. We have participated in a significant number of clinical trials published in peer-reviewed journals which were the basis for different FDA and EMEA approvals for anti-coagulants and antithrombotics for different companies. Another specialization is anti-infectives. This is an important country for anti-infectives in general, which includes AIDS. Also, immunology is a specialization of ours, and that includes disease areas such as rheumatoid arthritis, systemic sclerosis, psoriasis and Crohn's disease. We also work in the CNS area and in osteoporosis and diabetes. That therapeutic focus cuts across the medical department as well as clinical operations, which is important for areas like oncology or cardiology where there is a certain specificity of knowledge required at the tactical level, at the level

CWWeekly (ISSN 1528-5731)

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of the doers, who are the CRAs, project managers, data managers and biostatisticians. It's an added value for our clients because Pivotal can anticipate implementation and logistical problems during planning and avoid committing errors and/or anticipate solutions.

The third differentiator is our data management/biostatistics group, which local CROs in Spain do not usually have. Pivotal uses internationally validated tools, such as Oracle Clinical and SAS, that are accepted by regulatory authorities for submissions.

What clinical research conduct challenges does Spain have?

The most recent challenges are a result of the EU Clinical Trials Directive in Spain in place since 2004. From my perspective, things have improved dramatically in Spain. There is still work to do but, on average, the length of approvals of clinical trials—especially phase III trials, which used to take maybe six to eight months—have been reduced dramatically to about four months, on average. This is very competitive. Spain did not offer very competitive timelines before the Directive was implemented.

There are other areas that we need to improve on, such as the contracting process between hospitals and sponsors. All stakeholders are aware of this bottleneck and are working toward a solution. We have 17 regions in Spain and some regions have their contract templates at the regional level, but some hospitals have their own contract template. It's an educational as well as a bureaucratic problem, which must be solved if Spain wants to compete at the European and international level for clinical research. So the contracting process is still a challenge, but it is improving. Definitely the acceptance of a single opinion at the level of ethics committees is improving and is generally good.

The third challenge is the increased demand for CRAs because Spain, with more than 45 million inhabitants, has become more popular with biotech and pharmaceutical companies. There is more demand for clinical research in Spain and more

demand for well-prepared CRAs. Between 80% and 90% of CRAs in Spain are pharmacists, which is unusual to find in North America and the UK, where they are more often nurses. We have to work on increasing the clinical research training for nurses because I think they have a background well-suited to becoming a CRA, and that would increase the pool of CRAs in this country. Also, most of them are women who are 25 to 40 years old, which presents a challenge regarding their family commitments. We have to give them more support and flexibility.

What other changes have there been to Spain's clinical research landscape?

The biotech sector in Spain has increased quite significantly in the last five years and that has also created demand for CRO services. All these small biotech companies are either spinoffs from university departments or other public and private research centers. They do not have much structure for clinical research nor do they have much for a medical department. They need to outsource those services.

How has Pivotal grown and what are your plans for growth?

Pivotal has grown from about 20 people in 2002 to around 100 people currently. We have increased our number of clients from just one in 2001 to 49 clients now with more than 35 active accounts. About 80% of our business is repeat business. Our financial health and stability have also increased. We have some CRAs who are based regionally in the Valencia and Andalusia regions as well as an office with seven people in Barcelona in addition to the head office in Madrid.

We have established ourselves as an attractive partner in core therapeutic areas, especially oncology and CNS. We would like to take the next step, which is launching ourselves into a major commitment internationally. Pivotal won recently two important bids from biotech companies here, which required our services in other European countries.

After much research and many meetings, we have created partnerships with CROs in other European countries. The model for us is that Pivotal will maintain all leadership of the project. We are close to the biotech client in Spain so there can be more direct interaction with the project manager here. We do all the monitoring of Spanish centers. All data management and biostatistics are done here in Madrid. There is a global project manager who interacts with our partners in the selected countries—Hungary, Poland, France, UK, Italy, Germany Greece, among others. We will only outsource the field monitoring to those partners in the countries as well as the regulatory aspects. So, Pivotal has control over the whole project, and only the monitoring is sub-contracted to those partners as well as the approvals from ethics committees. This model has been working quite well for the clients as well as for Pivotal and the partner CROs. The next natural step would be to open some offices in other countries in Europe. This could be started as early as this year, with the first new office opened in Lisbon by the end of this year.

Other growth areas include converting Pivotal into a preferred partner for two types of companies. One is biotech or multinational companies that do not have a presence in Spain, but they want Spain and Portugal as part of their research countries. The other is CROs, especially North American CROs that do not have a presence in Spain. Instead of subcontracting with freelance CRAs in Spain, these companies could subcontract their business in Spain to Pivotal where they can maintain the global project management. We provide the field monitoring for them as well as all regulatory. Pivotal has been profitable from the first day. We have increased in size as well as attractiveness for the client without committing ourselves to too much debt for this growth. The next step is to convert Pivotal into the first internationalized Spanish CRO. We'll be working on that in the coming three years. That is one of our major objectives for our three-year plan.