

Parexel Spain â?? Pilar Rivas, Associate Director



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Pilar Rivas, associate director of global contract research organization Parexelâ??s Spanish affiliate, discusses cultural differences across Spain and their impact on clinical trials, as well as the world-class infrastructure that allows CROs in Spain to perform high-quality research.

Do you feel that supporting clinical research is a priority for the Spanish government?

I believe supporting clinical research is a priority for the Spanish government. The government is aware of Spainâ??s many medical professionals, investigators, pharmaceutical companies and general experts with a sufficient patient population to support the clinical research world here.

How does Spain fit as a regional hub for clinical research?

Spain, in general, has a consolidated public health system. Within this, there are large hospitals with solid expertise and a variety of ambiances plus a significant patient population covering a variety of cultures. That is important because Spain is thus in a good position to compete with other European countries for clinical research because of the diversity in our patient population and the ability to undertake clinical trials of any scale in our hospital system.

How would a CRO like Parexel adapt to cultural differences in Spain?

Most importantly, we need to adapt to the languages and cultural differences throughout Spain. Castellano is the primary language but there are others that we have to use in the clinical trial world, as not all patient populations are able to speak the same language. There are also different cultures between those living in cities and those in villages in Spain.

What is your assessment of Spainâ??s transparency for regulatory framework?

The startup of one clinical trial depends on the country. It could be complicated and long. However, this process is improving year by year. Parexel, for example, is working on faster and simpler procedures. Additionally, we will soon have a new European law in which we can simplify many processes.

Parexel offers a very extensive range of services; how important is sales and marketing for product launches in Spain?

Parexel is involved with international clinical trials and Spain participates in the same ways as the US or Canada does in the development of a drug. Our participation is the same as other countries. We are an international company and our development is always international.

As recessions often mandate outsourcing, have you seen an increase in business here in Spain?

More and more, we are seeing pharmaceutical companies outsourcing clinical trials to CROs. This is because CROs are specialized to develop clinical trials. We can offer pharmaceutical companies expertise, higher quality and shorter timelines. That means that we can contribute to their success more and more. Spanish pharma companies are externalizing many operations as well. This is being done generally in all countries, not just in Spain.

What unique characteristics does Spain's research scene have?

Oncology and infectious diseases are very strong therapeutic areas in Spain. We also have important key opinion leaders that help contribute to the development of future drugs.

In addition to this, Spain features a large public hospital network, which is increasingly interested in doing clinical trials.

Parexel services companies in the pharmaceutical, biotech and medical device industries. What areas are you most active in?

In Spain, we primarily work in pharmaceuticals and biotech. Medical devices do contribute as well, but the volume of work is less in Spain.

What are some key trends?

One critical investigator in Spanish clinical trials recently mentioned that biotech companies in general have interesting, innovative drugs with positive results. That means when you offer one clinical trial with a really interesting drug in the market to a pool of investigators they are very positive about doing clinical trials. Biotech companies are very small and they need global CROs like Parexel to help develop the drug in different countries.

What successes have you had with companies developing their drugs in Spain?

Getting the desired number of patients for trials is a success in itself. We are putting clinical trials in place, getting the target number of patients as soon as possible, shortening timelines and working with quality to develop drugs.

A Spanish biotech company might not be able to get that number of patients necessary. How integrated is Spain with the rest of Europe for joint international collaborations?

All investigators and groups of investigators participate in international networks and they are involved with many international initiatives. Their know-how is the market, outside of Spain, which

drugs will be developed and they might be interested to participate in the trials. It is important to get the commitment of the best investigator interested in doing clinical research to participate in the trials, make expectations and to contribute.

How do you do that? What does Parexel offer that sets it apart to get these key investigators and necessary patients?

Having been in Spain since 1996, we have accumulated local knowledge while also gaining important experience and expertise. We know which investigators and hospitals are the best in recruitment, investigation and quality, and we go to these investigators and sites to develop our clinical trials.

Where do your clients generally need the most help?

Many of our clients are seeking expert resources and global coverage.

How important is Spain within the context of Parexel in Europe?

Spain is a key country for us.

Where do you expect the industry to go in the next five to ten years?

The evolution involves getting investigators more prepared with more knowledge. . The development of international CROs and pharma companies will also continue to improve.

What are your own personal ambitions for developing this affiliate in the future?

I would like to continue growing the expertise network that Parexel Spain has developed, hiring qualified individuals right out of university and retaining our current base of experts. It is also important for us to maintain and continue to develop a solid management group, to reinforce and guide the local staff.

As infrastructure grows, what is your strategy to stay at the same speed of development in the country?

We strive to continually achieve high customer satisfaction scores, working with our clients to meet expectations.

What would you like to achieve in the next five years?

We currently have 240 employees in Spain; I would like to see this increase exponentially. I have been with Parexel Spain for 16 years, and when I first joined, it consisted of only 20 people. We have developed not only the clinical operation department, but also the breadth and quality of our clinical trials.

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