Rosa Gonzalez Galindo – Senior Vice President of Clinical Development and Responsible for Global Immunology and Inflammation Development, Syneos Health, Spain

Because our clinical and commercial experts live under the same roof, they are able to constantly share real-world knowledge and insights that lead to getting the job done better, smarter and faster increasing the likelihood of regulatory approval and maximizing commercial success

10.07.2019

Tags: Spain, CRO, Syneos, Clinical Trials, Research

Through a merger between INC Research and inVentiv Health in 2018, Syneos Health has become the industry's only fully integrated biopharmaceutical solutions organisation which includes one of the world's top three global clinical research organisations (CRO) and a contract commercial organisation (CCO). Rosa Gonzalez Galindo explains the scale and scope of Syneos Health's services, along with the key success factors for the company both now and for the future.

What is the main motivational factor that drives you to continue working in clinical research?

Working in clinical research is very rewarding because we can develop new treatments that support patients to have better lives. I have been lucky enough to have participated in the development of several products that have changed people lives, and that is something I feel very proud of. At Syneos Health we have the capacity to support pharmaceutical companies in the journey to bring a product from the lab to the patients – this includes translational research, clinical research and commercial services. I feel fortunate to work in clinical development and at Syneos

Health.

What has been the impact of the 2018 merger between INC Research and inVentiv Health on the Spanish affiliate?

Most of the benefits of the merger are global, we have a very similar structure in Spain to what we have worldwide.

Our merger allowed us to purpose-build an organisation that helps biopharmaceutical customers navigate today's challenges. We are the only organisation that brings together a contract research organisation (CRO) and a contract commercial organisation (CCO). This means that we are able to provide customers with best-in-class clinical research and development and translational medicine, but we also have a leading commercial organisation offering consulting, communications, selling and value and access services. This depth of expertise allows us to fully support our customers across the entire product lifecycle – from developing products to driving the commercial launch, and beyond.

In Spain, in particular, we have medical zones and commercial consulting, which utilize our knowledge of regional regulatory bodies and payers to help our customers position their products for commercial success.

How do you think your capabilities compare with those of your competitors?

Syneos Health is a good partner to those companies that wish to develop or bring products to market. Our company includes one of the world's top three biggest CROs and the biggest CCO, offering services from translational science, full-service CRO studies, commercial services, including medical science liaisons (MSLs), salesforce, advertising, public relations, commercial consulting and adherence programming.

Because our clinical and commercial experts live under the same roof, they are able to constantly share real-world knowledge and insights that lead to getting the job done better, smarter and faster increasing the likelihood of regulatory approval and maximizing commercial success. For example, by sharing commercial and market insights earlier in the process, we can improve clinical trial design and accelerate patient recruitment. It's a powerful platform for customers of all sizes.

Why are CROs evolving from simply running clinical trials to providing evidence themselves?

Developing and brining a drug to market requires experts to help biopharmaceutical companies maximize the effort and minimize the risk.

At Syneos Health, in the last five years, we've supported the development or commercialization of 91 percent of the new medicines approved by the FDA and 90 percent of the drugs granted marketing authorization by EMA. By tapping into Syneos Health, biopharmaceutical companies can access the countless lessons we've learned during this extensive work experience and gain a partner with strategic and operational excellence.

Given that you can perform these tasks for all sizes of companies – from a one or two-person biotech to a large multinational company – how does your client portfolio in Spain look?

We work with customers of all sizes. In Spain we have a similar distribution of clients, we work for Spanish pharmaceutical companies and small biotechs but also have a strong relationship with the affiliates of big pharmaceutical companies, providing them with the services they need for the Spanish market.

Our depth and breadth of expertise allow different sized companies to tap into us in a way that fits their needs. Smaller, innovative biotech companies for example may work with us to access many capabilities and allow us to help them scale their teams without having to build up an infrastructure. We can work with larger companies to maximize return on investment by implementing cost-reduction strategies and increasing th efficiency of the drug development and commercialization process.

How attractive is Spain as a clinical trials destination?

Spain is one of the key pharmaceutical markets in Europe and the world. We are very efficient on submissions and approvals and are one of the fastest to activate sites, in comparison to other European countries, thanks to the harmonization of processes across the different regions. The new Royal Decree has supported us in being much more efficient in terms of getting approvals from ethical committees and the Ministry of Health.

From a site perspective, Spain is a great country to work due to the level of expertise of the investigators. Furthermore, we have an excellent health system. There are several therapeutic areas where we have worldwide key opinion leaders in Spain that support global development plans, not only participating in the clinical trials but also as experts on advisory boards.

The only challenge that we have is at the time of negotiating contracts. This depends on the flexibility of the legal department of our sponsor in terms of contract language negotiation.

How easy is it to find and recruit rare disease patients, given that there is no centralised registry?

We take a patient-focused multi-channel approach. Although the registry is not centralized, we have national reference networks for different rare diseases. We also tap into key reference hospitals that are targeting all of the patients referred from other autonomous communities in a given disorder. In the rare disease space, we also find patient advocacy groups to be a valuable resource in the identification and referral of the patients to the investigators that are participating in the studies,

How fit for purpose is the way we currently conduct clinical trials for the next frontier of medicine?

We are moving away from the age of large trials searching for the next blockbuster drug to the era of precision medicine. We are now focusing on targeted therapies with better efficacy and fewer side effects. Gene and cell therapy and immunological research are examples of new research models that are available.

Technology and data is also evolving to meet the needs of these new types of trials. Integrated systems facilitate tracking the data from investigators and patients, and we can have visibility in the data faster. This transparency and real-time access to data allows us to minimize the risk for the patients participating in the trials and make decisions earlier.

As personalized medicine evolves, sample sizes are decreasing and late-phase, trials are increasing in importance. In late-phase trials, we can compare real-world data with patients on treatment minimizing the number of patients needed in the comparator groups, and decreasing the risk for the patients, and the cost of the studies.

Our late-phase trials are helping us to bridge the gap between clinical research and the final product in the market.

What is the significance of Spain to Syneos Health's global operations?

Spain is an important market with excellent investigators and increasing investments from pharmaceutical companies. At Syneos Health we have a large presence in Spain with 715 employees in four offices across the country, including in both Madrid and Barcelona, and we continue to grow. We have employees specialized in project management, monitoring, regulatory affairs, and commercial. One of our biggest groups in Spain is a resourcing group that provides clinical development professionals to the affiliates of big pharmaceutical companies. Most of the global departments at Syneos Health are represented in Spain.

What makes you the partner of choice for pharmaceutical or biotech companies?

There are three points that differentiate us from our competitors. The first is our biopharmaceutical accelerator model that allows us to support clients across the entire drug development and commercialization continuum.

The second key strength of Syneos Health is that we are therapeutically aligned. We have dedicated business units focused on CNS, Oncology and General Medicine. All employees in each of the business units, from the business unit head to the clinical research associates (CRAs) are specialized therapeutically.

The third differentiator is The Trusted Process, our proprietary, metrics-driven methodology initially developed to manage all aspects of clinical studies. This unique, four-step approach delivers faster results while maintaining data integrity and reducing operational risk and variability.

In the next three to five years what would you like to see Syneos Health achieve?

I hope to see Syneos Health as the leader in the biopharmaceutical market, supporting our customers to bring their products from lab to patient.

I would like to see more biopharmaceutical customers take full advantage of the benefits of having a partner like Syneos Health and the global services we can provide – from lab to life.

What is your final message on behalf of Syneos Health?

We have a passion for improving patient lives and can provide therapeutically focused global teams to support your company in the development and commercial success of your product.

See more interviews