

# Clinerion enters an improved clinical trials market in Brazil

By Marilyn Fenichel

In mid-December, **Clinerion**, a patient recruitment company, made its entrance into the clinical trials market in Brazil. With a state-of-the-art patient recruitment system (PRS) that has a track record of rapid identification of eligible patients in other markets, Clinerion is poised to make a significant difference in Brazil.

To strengthen its presence in this new market, Clinerion has forged a partnership with the **iHealth Group** of Brazil, which operates 40 hospitals, with a total patient population of 25 million. The iHealth Group's role is to make consistent quality electronic health records (EHRs) data available, significantly broadening the number of patients who could potentially participate in trials.

"What sets our system apart is our capacity to find patients based on real-time EHR data—with no guesswork," explained Ulf Claesson, Clinerion's CEO. "A protocol within the PRS system can be coded so that all connected hospitals can be searched by diagnoses, treatments, medications, demographics and lab values at the same time, returning results in minutes rather than the weeks or months it can take if done traditionally. Our approach has proven to be a game changer in other markets."

Indeed, this way of recruiting could have a similar impact in Brazil. According to Douglas Andreas Valverde, CEO of **Techtrials**, the largest full-service CRO in Brazil, EHRs in hospitals in Brazil are not yet standardized. "There are five to 10 different systems running, and they are not integrated very well," he said. "Trying to organize these systems could turn out to be a beneficial step for the whole market."

Yet in a culture used to the personal touch, depending on EHRs for patient recruitment may take some time. "Physician-patient relationships are based on trust, and patients may be more open to the idea of a clinical trial if it is recommended by their physician," said Federico Lerner, Ph.D., senior director of operations, Latin America, for **PRA Health Sciences**.

Nonetheless, Clinerion has a sound system in place, including ensuring that throughout the query process, individual patient data remain confidential, never leaving the hospital environment. "When a potential clinical site with a suitable population has been identified and selected by the pharma company, the company takes over and contacts the hospital directly to contract the clinical trials," said Claesson. "The hospital then takes the lead in the enrollment process."

These promising developments come at a pivotal moment in the Brazilian clinical trials market. Over the past eight years, growth in the market has been experiencing a downward trend. *The CenterWatch Monthly* published a comprehensive examination of declining growth in emerging markets, including Latin America, in March 2016. "Currently, Brazil has only 1.5% of the clinical trials globally, compared to a projected 4.5% to 6%," explained Valverde. "We would like to run more trials, but prospective clients are running away because of our long regulatory timelines."

Part of the reason for the delay is that multiple layers of approval must be ob-

tained before the trial can begin. Applicants must receive approvals from the local ethics committee and the national ethics committee, **CONEP**, before it can be considered by the **National Health Surveillance Agency** (ANVISA), which is connected to the **Ministry of Health**. Final approval for clinical trials rests with ANVISA, where the process can take as long as 18 months.

But the situation may be undergoing changes for the better. New regulations were approved in 2015, and a new clinical research law is now under review. The law has already been passed by Brazil's Senate and is expected to be approved by the House of Representatives in mid-2017. "These changes should improve the regulatory environment significantly," said Valverde. "We hope to see the number of clinical trials jump from the current level of 1.5% to 3.5-4%."

In fact, Techtrials may already be reaping the benefits of the improved regulatory environment. **Bird Rock Bio**, a clinical stage biopharmaceutical company based in La Jolla, California, just received approval for a 200-patient, phase II clinical trial for gerilimzumab, a novel therapeutic antibody used to treat rheumatoid arthritis. This study was specifically designed for the 1.2 million patients in Brazil suffering from this disease.

"This is an example of the kind of clinical research that is possible in Brazil, which has a large population, qualified sites and strong investigators," said Valverde. "We can also run trials at a competitive price."

These improvements are a promising

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sign, but there are other issues that also need to be addressed. An important one is the role of social media in patient recruitment. "There's potential here for social media to serve as a link among clinical trials, medical needs and subjects searching for available trials," said PRA Health Sciences' Lerner. "Right now, the environment is naïve.

Moving forward, the industry needs to discuss the role we would like social media to play in our work."

While acknowledging remaining issues that need to be addressed, with regulatory hurdles topping the list, Clinerion is nonetheless optimistic about its new role in Brazil. "We're already seeing an improvement

on the regulatory front, and we believe that remaining hurdles will be removed over time. We will be ready when change comes," said Claesson.

"The sky's the limit," Claesson concluded. "We expect the greater visibility brought on by Clinerion will change the landscape in Brazil." 