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Miami-based consultancy bringing more U.S. startups' phase I trials to Colombia

By Ronald Rosenberg
CenterWatch Staff Writer

In an effort to attract entrepreneurs who will conduct clinical trials and expand their commercialization efforts in Latin America, Colombia has signed an alliance with **Interventional Concepts** to recruit U.S. and European drug and medical device startups to conduct early stage trials for drugs and medical devices.

Colombia already is considered the sixth leading clinical trials provider in Latin America, with 120 GCP-certified research centers and 63 institutional ethics committees, the equivalent of IRBs.

Interventional Concepts already has had some successes, including **MitroSpan**, a Boston-area company developing a cardiovascular device. According to MitroSpan founder and CEO Jon Rourke, the company has chosen to conduct its phase I trial in Colombia because of lower cost, ease of patient recruitment and streamlined approach to launching studies.

"When it comes to launching early clinical trials for medical devices, the three leading Latin American countries are Colombia, Paraguay and Chile," said Rourke. "Small device trials are very individual; you work patient to patient. Colombia also is relatively close to the East Coast with short flights, has a stable government and is the only country trying to attract startups and small companies for phase

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iCardiac launches risk-sharing program guaranteeing accurate and complete studies or sponsors don't pay

By Ronald Rosenberg
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With the **FDA**'s recent go-ahead for earlier cardiac safety testing, **iCardiac Technologies** has announced a risk-sharing program with sponsors that guarantees sponsors will receive precise, conclusive Thorough QT results—or pay nothing for iCardiac's services.

Based on study size, those services can cost from $300,000 to more than $1 million, according to Alex Zapesochny, president and CEO of iCardiac Technologies, a large, dedicated electrocardiogram (ECG) core laboratory serving the pharma industry.

In cardiology, the QT interval is a measure of the time, in milliseconds, between the start of the Q wave and the end of the T wave in the heart's electrical cycle. It represents electrical de-polarization and re-polarization of the heart's ventricles and provides doctors with essential information: if the interval occurs in a normal amount of time or if it takes longer, based, in part, on age, sex and regularity and speed of the heart.

Long QT syndrome reflects abnormalities in the heart's electrical recharging system. A prolonged QT interval may be due to an underlying medical condition or induced from a medication. Careful measurement of the QT interval during a clinical trial detects

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Colombia

l. It is harder and more costly to do early stage trials in the U.S., and Colombia hospitals and some doctors have close relationships with the **University of Miami Medical School**, a teaching hospital."

Interventional Concepts, founded in 2010, is a clinical research consulting company based in Miami. Since signing the alliance with the Colombian government last December, it has worked to partner innovative device and biopharma companies with more than 120 research centers in Colombia.

Colombia is among six Latin American countries that have seen significant growth in clinical trials—along with concerns about meeting timelines and gaining regulatory approval. Collectively, the countries provide Principal Investigators (PIs) access to thousands of patients, many of them treatment naïve and trial naïve—factors that explain the high success in patient enrollment and retention.

"Traditionally, Argentina and Brazil have well-established track records for conducting clinical trials. Recently, we have seen increased recruiting capabilities and clinical trial activity in Colombia and Chile, to name two," said Paul Evans, vice president and global head, feasibility and enrollment solutions at **Parexel**. "Countries in Central America frequently give good results, but they do not have the scale of the aforementioned countries."

Overall, Latin American clinical research has increased in recent years, as the region offers a combination of trial-naïve patients, well-qualified PIs who are knowledgeable about Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines, and strong physician-patient relationships. Despite regulatory delays and bureaucratic challenges, some countries have made strides in improving regulatory environments to shorten study start-up.

"In Brazil, the time it takes to get a study approved and recruit patients has improved, but it is still our Achilles heel, although there is better awareness of the problem and the government is working on it," said Vitor Harada, **Quintile**s' regional business head for Latin America.

Brazil's regulatory timeline for launching a clinical study is about 10 months, compared to Colombia's three to six months, said Harada. The goal, he added, is for Brazil to get to four to six months. Already, some studies that have gotten the green light to enroll patients in eight months.

"There is better awareness and more media attention on the problems, which have led to clinical research alliances in Brazil that bring together CROs with drug companies, investigators, patient groups and clinical professionals," he said.

Other changes include different paths to protocol reviews between local health committees and Brazil's national regulators, expected at the end of this year, said Harada, adding that the government also is working to improve the nation's biopharmaceutical industry.

Many physicians in Latin America view participation in clinical trials as an attractive opportunity, partly because access to large patient populations makes recruitment easier and retention stronger.

The combination of good healthcare (95% of Colombia's citizens have health insurance), an already strong clinical trials industry, stringent regulations issued in 2008 that require sites to be certified by **INVIMA** (Instituto Nacional de Viglancia de Medicamentos Alimentos) and a relatively quick and predictable approval process for launching a trial has made it a desirable clinical trial destination.

Pedro Martinez-Clark, chief medical officer of Interventional Concepts, said two years ago he saw the next generation of small medical device and pharma startups flying to Europe for early phase clinical trials, which he viewed as a missed opportunity for Colombia.

"Outside of Brazil, there wasn't much interest in medical innovation, and we decided to go after U.S. entrepreneurs and small companies looking for low-cost ways to get phase I approval as an alternative to traveling to Europe," said Martinez-Clark. "So we found some companies, such as MitraSpan, which also found traveling to Colombia both less expensive and less time consuming than Europe."

"So far, we have not seen other Latin American countries looking to discover what we have found in small companies," he said. "Of course, we realize that some of the more advanced clinical trials will return to the U.S."

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