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CONDUCTING CLINICAL STUDIES IN LATIN AMERICA

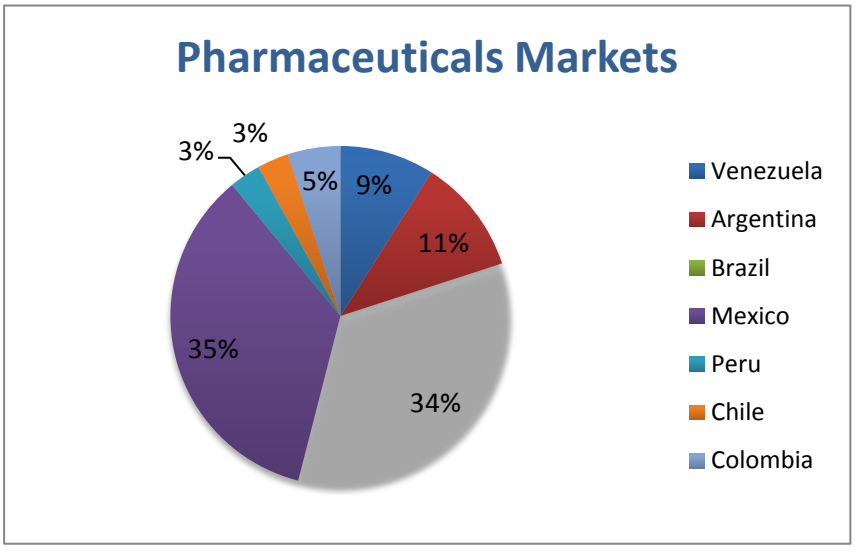
1. WHY LATIN AMERICA?

Latin America is considered a region with many possibilities and **the opportunity** for clinical research offering:

- Guaranteed recruitment and retention rates without compromising the quality of the data, with associated cost efficiency.
- Adequate communication and IT technology at most sites, many Investigators trained in USA or Europe.
- Bilingual Clinical Research staff trained and experienced in ICH GCP regulated research.
- Active Regulatory Agencies overseeing Research activity for 20 years and aligned with ICH GCP guidelines.

For this reason, of major pharmaceutical companies and CROs are present in Brazil, Mexico and Argentina. A long list of advantages to performing clinical research in Latin American countries includes:

Substantial Markets for Product Sales. The approximately 600 million people of Latin America represent a sizeable market for approved drugs. IMS Health has estimated that the region will generate 10% of global pharmaceutical sales by 2017.



Source: Julianne Lewis. International Regulatory Affairs. John Hopkins University

Non expensive operative costs for clinical research services. Decreased travel to and from sites (densely populated cities). Multiple academic, public and private hospitals in small areas. Salaries and Professional fees for Researchers and medical procedures involved in research highly competitive compared to those of USA/Canada/Europe. Reference Sites concentrate less prevalent diseases, helping optimize costs and simplify site selection. When running multi country studies in the region, translation costs are minimized since Spanish is the prevailing language spoken in the region followed by Portuguese (Brazil).

Outstanding Environment for performing quality clinical research. Quality proven regional vendors for support services: couriers, warehouses, regional and national central labs and investigator meeting locations.
There are also Clinical Research Professionals Certification and at University level Post Graduate courses, such as Clinical Research Masters Degree available locally since 2007.
Highly controlled regulatory environment aligned and experienced with ICH-GCP guidelines compliance (e.g. in Argentina and Brazil since 1996).

The continent's time zones are convenient for interactions with headquarter offices of North American and Europe companies (5 hour difference or less).

An Enthusiastic and Qualified Investigator Community. Physicians in Latin America are trained in the highest medical standards and appreciate the opportunity to enroll their patients in studies that involve the latest treatment advances. Participation in studies also brings to physicians and medical centers a degree professional prestige and a welcome source of additional income.

Adherence to ICH GCPs. Latin American governments have been consistently promoting regulations that adhere to legal and ethical international standards, and facilities are routinely audited for compliance.

FDA Inspections. No country has had OAI Results in the last 10 years (2006-2016)

Country	# Inspections (% OAI)	% VAI
Brazil	**41** (0%)	41,46%
Mexico	**17** (0%)	58,82%
Argentina	**40** (0%)	27,50%
Chile	**6** (0%)	16,67%
Peru	**5** (0%)	60,00%
Colombia	**3** (0%)	33,33%
Panamá	**0** (0%)	0,00%
Costa Rica	**1** (0%)	0,00%
Paraguay	**1** (0%)	100%
Ecuador	**1** (0%)	0,00%

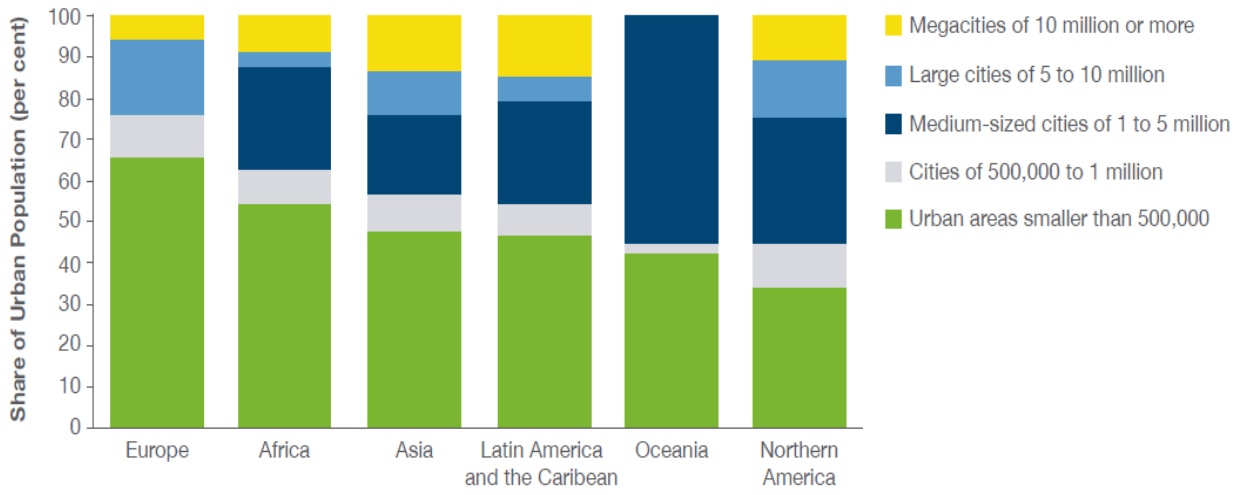
Source: http://www.accessdata.fda.gov/scripts/cder/CLIIL

Outstanding Environment for excellent recruitment performance. Large, ethnically diverse population. Latin America has wide diversity of races and ethnicities which mirrors the wider market. There are increasing access to healthcare and medications. The region is a complementary site to northern hemisphere sites for indications with seasonal variations (such as respiratory diseases). And also, it is a favorable niche for emerging and neglected diseases.

Willing and compliant patients. Latin Americans are, generally, eager to participate in clinical trials when their physicians recommend doing so. The strong physician/patient bond that exists in the region also strengthens patients' compliance and retention in the trial.

Easy access to patients. The fact that most Latin Americans live within large urban areas means that recruitment efforts and trial logistics can be concentrated and simplify. This is, in fact, a major source of cost savings

The Most Urbanized Area of the World Latin America is home to dense urban areas; in fact, the United Nations has referred to it as the most urbanized region of the world. Overall, 80% of Latin Americans live in cities, and the urbanization process is expected to continue. The United Nations estimates that by 2020, 90% of the people in the Southern Cone region will live in cities. Many of the major cities date back to the efforts of Europeans to colonize the area in the 16th century. Sao Paulo (20 million), Mexico City (19 million), Buenos Aires (13.6 million) and Rio de Janeiro (12 million) all rank in the top 25 largest metropolitan centers in the world. **Source:** World Urbanization Prospects: The 2014 Revision, Highlights

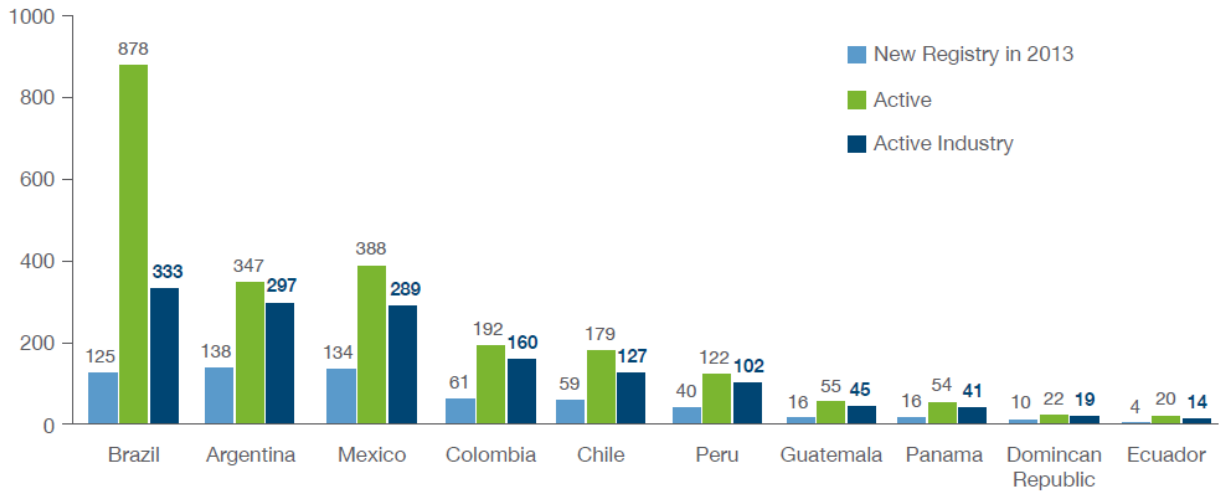


Population distribution by city size varies across major areas in 2014

An Active, But Far From Saturated, Trial Market

In terms of its capacity to accommodate clinical trials, Latin America is, potentially, at an ideal stage: it has the requisite staff, facilities, regulations and quality standards, but is not yet saturated with trials. Currently there are 1,427 active industry studies in progress across ten countries in the region, and six countries (Brazil, Mexico, Argentina, Chile, Peru and Colombia) account for nearly 90% of all Latin American trials. (See Figures 9 and 10) Brazil, in fact, accounts for nearly one-third of all trials in

the region, which is not surprising given the size of Brazil's pharmaceutical market. IMS Health has forecasted that Brazil will be the 4th largest pharmaceutical market in the world by 2017. **Source:** clinicaltrials.gov Oct 13, 2014



Lower density of research studies leaves room to grow maintaining subjects participation rates.

Region	Number of Studies Analyzed	#of recruited subjects	% of recruited patients	Patients per million citizens
Latin America	161	23 341	7.5%	46
USA	181	40 433	12.9%	133.1
Australasia	185	9 653	3.1%	140.8
UK	173	16 873	5.4%	276.9
Canada	191	14 695	4.7%	442

Source: Leem- Leem Recherche. Place de la France dans la Recherche Clinique Internationale Enquete 2008. Paris 10 October 2008

2. WHY AICROS?

AICROS, the alliance of International CROs, is a network of local & well established CROs businesses providing full range clinical research services on a global scale. We combine the multinational coverage of global CROs with the customized service and flexibility of local service providers. Contact us now for more information and any questions about clinical trials.

Bibliography:

- **World Urbanization Prospects: The 2014 Revision, Highlights**
- **Clinicaltrials.gov Oct 13, 2014**
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