

## ABOUT LATIN AMERICA

Latin America, a geographical area with over 500 million inhabitants, has 1.5 times the population of the USA and around the same number as Europe.

This part of the globe occupies a strategic position as a location for clinical trials for a number of reasons:

- Population concentrated in large metropolitan areas
- Potential for recruitment in tropical and rare diseases and added potential for all other diseases
- Large number of treatment-naive patients
- Great ethnic diversity

In recent years, the major economies of the region have demonstrated political stability and exceptional growth.

South American countries have managed to prepare to host research projects and have created better conditions for global competition.

They have invested in the physical infrastructure of health networks, the preparation of professionals and research teams, integration with other world regions – a factor that enriches not only culture but also genetic diversity- and the development of institutions.

With diseases from both the old and the new worlds, Latin America has a high consumption of pharmaceuticals and has a potential for even more.

Latin America pharmaceutical sales grew almost 13% compared to an 8% increase for North America. Brazil and Mexico are the two largest markets by sales, but between 2002 and 2006, growth of the Brazilian market was almost three times that of Mexico. Argentina was the second fastest growing market over the same period (almost 20%).



## ABOUT BRAZIL

### The Patients You Need, the Expertise You Want.

Brazil is home to one of the largest and fastest growing pharmaceutical markets in the world. Our clients know also that Brazil has a rapidly growing market for clinical services.

Sponsors have discovered that Brazil provides unique advantages during the clinical trial process. Brazil's large and highly concentrated patient populations, its low per-patient cost, and world-class healthcare facilities combine to make Brazil an ideal site for studies in many therapeutic areas.

Data from the Swiss State Secretary for Education and Research SER presents the annual growth in the number of scientific publications 2000-2006 in %: Brazil has one of the highest growth rates compared to other countries.

China	18.6
Turkey	18.1
South Chorea	13
Taiwan	10.8
<b>Brazil</b>	<b>10.4</b>
India	8.9
Spain	6.7
Italy	5
Netherlands	4.3
Switzerland	3.8
USA	2.7
Germany	2.1
France	1.8
Great Britain	1.4
Japan	0.8

This improvement in the scientific output ranks Brazil as the most productive country among the Latin American nations.

## Top Five Advantages in Brazil

- 5th most populous country – over 190 million inhabitants
- 80% of population concentrated in major metropolitan areas
- Disease specific hospitals – speed and simple recruitment
- Access to large patient populations – Oncology, CNS, Cardiovascular Diseases, Diabetes
- Significant treatment-naïve population

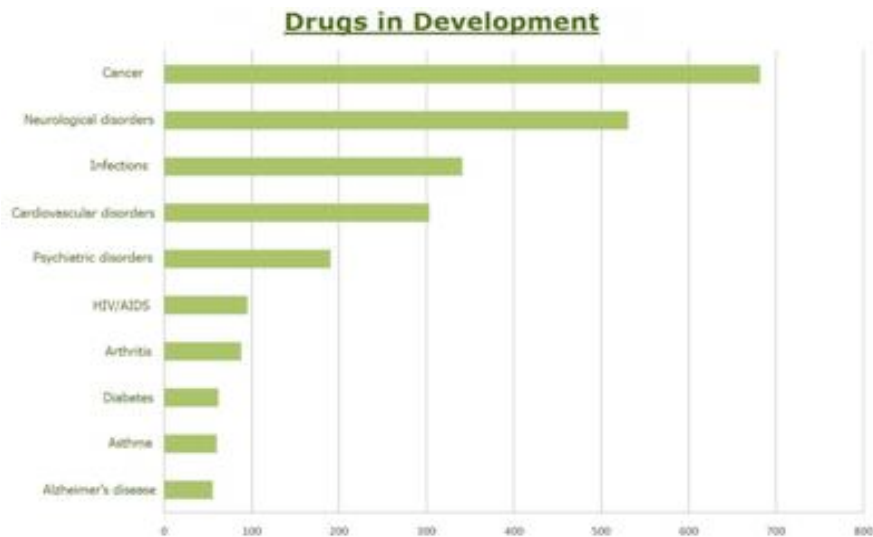
Leading foreign pharmaceutical companies are strengthening their operations in Brazil. Daiichi-Sankyo, the only Japanese company with manufacturing operations in Brazil, is expanding its plant. GlaxoSmithKline has announced a multi-billion alliance with Fiocruz's Bio-Manguinhos to develop vaccines. Nycomed has announced investments of US\$300.0 million over the next five years. Novartis is setting up a vaccines plant. Brazil is the most important BRIC market for Sanofi-Aventis. The company has increased its market share following the acquisition of Medley and has announced its plans to create a plant for the production of generic contraceptives. Solvay has announced the creation of a new share services center. In the wholesale sector, Celesio, the largest European wholesaler, has acquired a majority state in the Panpharma group. Other companies are re-assessing their operations. Boehringer Ingelheim, for instance, has signed a third-party manufacturing agreement with Zambon, while Roche has announced plans to sell its manufacturing plant in Brazil.

Manufacturing investments continue to help increase market positioning locally and internationally. Biolab plans to create a new R&D center in 2010. Cristália has inaugurated a new R&D center; the company claims to be the local producer with the highest R&D portfolio and investments. EMS is investing in a new Drug Delivery Systems (DDS) platform. Eurofarma continues to invest in its animal health division in the local market, while it has acquired an Argentine pharmaceutical producer in order to develop its international operations. Hipolabor is building a second manufacturing plant for the production of antibiotics. Even public producers follow the same trend. Fundação para o Remédio Popular (FURP), for example, has inaugurated a new manufacturing plant for the production of generic medicines, the first of its type.

## CLINICAL TRIALS IN BRAZIL

Eurotrials serves the type of companies who anticipate marketing in Brazil and need local data, or just want to be sure there are plenty of patients to complete each study.

Most big Pharmaceutical companies already have a degree of ongoing clinical development in the region, and Brazil is a mandatory country.



Sponsors recognized that Brazil's large patient population makes it both an important market and an excellent place for clinical studies. Having at least one Brazilian site in a global study ensures that recruiting patients will not be a problem.

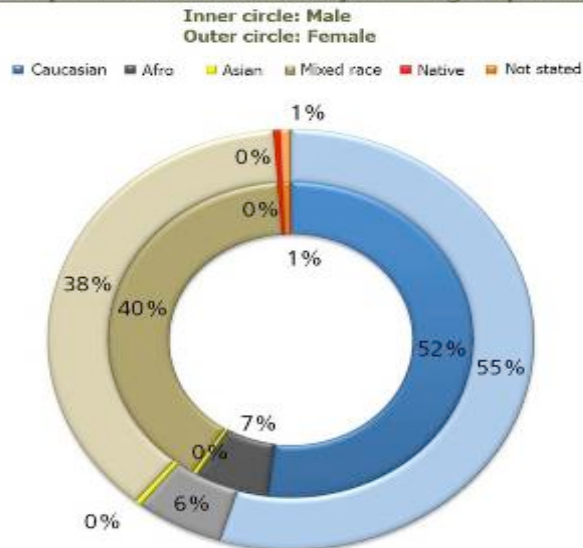
Brazil is also less complex than many other emerging markets. Unlike Europe and Asia, Brazilian patients all speak the same language so translation into multiple languages is not an issue.

Another important advantage is that Brazil is in the southern hemisphere making it ideal for year-round seasonal studies when combined with sites in the northern hemisphere. Sao Paulo is just one hour ahead of US Eastern Time, making communication quick and simple.

## Capacity and Diversity

Brazil is the 5th most populous country in the world with an estimated 190 million people. Thanks to ethnic diversity, heterogeneous epidemiological profiles and a willingness to participate in clinical trial programs, Brazil is a tremendously attractive market for clinical research.

**Brazilian Population Distribution by Ethnic group x Gender**



The Brazilian population is also very diverse, including both young and old. It is estimated that 25% of the population is under the age of 14, making it an excellent location for **pediatric trials**.

Brazil has the largest ethnic **Japanese population** outside Japan and data from studies conducted in Brazil are acceptable to the Japanese Ministry of Health making Brazil an excellent location for bridging studies. Brazil also has a high incidence of certain rare and tropical diseases allowing for research in such areas as dengue fever and malaria.

Eighty percent of these people are located in close proximity to a large metropolitan area making it easy for them to gain access to a clinical trial.

Because of the interest in receiving the best possible medical care at affordable prices, patients are eager to participate in clinical trials and Eurotrials' patient retention rate is consistently above 90%.

## Clinical Research is Thriving in Brazil

In 2008, the cost per patient for trials in Brazil was approximately 30% less than the cost in the United States of America. More importantly, Brazil enjoys a major advantage in recruiting patients for Oncology, CNS, Cardiovascular Disease, and Diabetes. Because of this, Brazil is expected to receive a large and increasing share of the clinical trials conducted outside the United States of America.

Brazil has a nationwide public system policy for oncologic treatment. There are population based studies going on in 22 centers, located in capital cities, where data is being systematically collected, stored and analyzed.

Data on 2010 cancer incidence (Brazilian National Cancer Institute) estimates: 489,270 new cases expected (excepting skin non melanoma- type tumors). The most numerous will be prostate and lung cancers in men and breast and uterus/ cervix cancers in females: 236.240 new cases in males and 253.030 in females. Following these will be: prostate cancer- 52,000; breast cancer – 49,000; colorectal cancer – 28,000; lung cancer – 28,000; stomach cancer – 21,000; & uterus/cervix – 18,000.

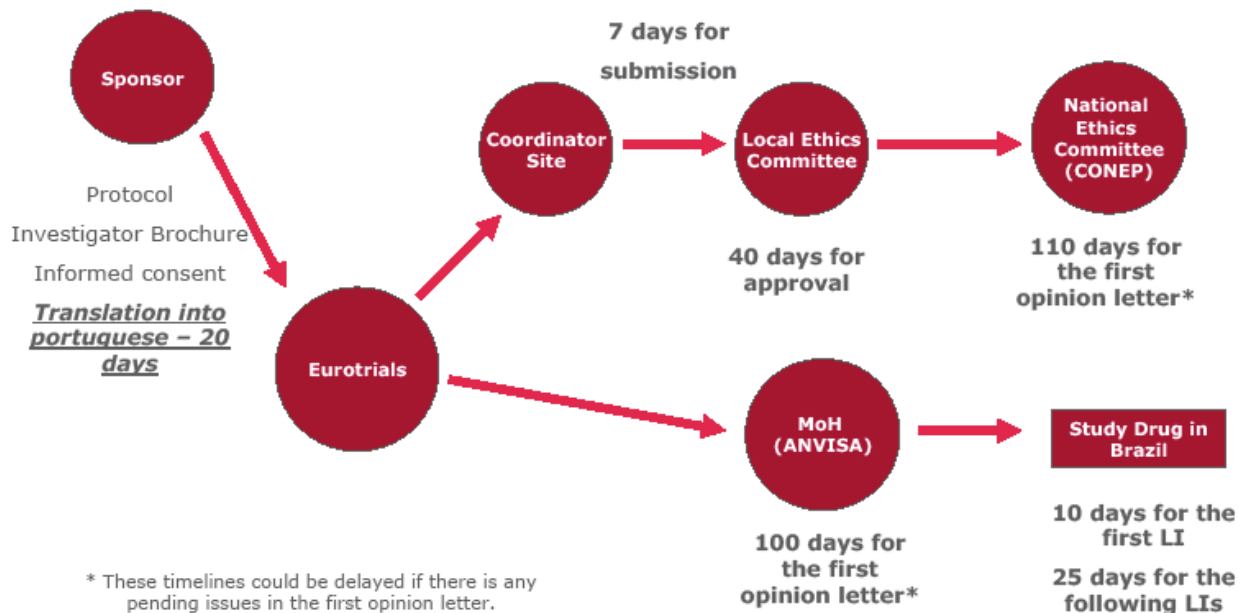
Add to that its expected market growth rate of approximately 12% for 2009 and you have an emerging country with the potential to contribute large numbers of patients eager to participate in clinical research in a market that is expected to outpace growth in the USA by almost 10%.

Sponsors from around the world recognize the importance of the Brazilian market and the growing opportunity to conduct studies within Brazil.

## REGULATORY PROCESS IN BRAZIL

In July 2008, the Brazilian regulatory agency, ANVISA, changed the regulatory process to allow sponsors and CROs to pursue separate ethics committee approval requests simultaneously to the ANVISA submission, instead of sequentially. This shortened the approval process, reducing the time from final protocol to first patient, first visit.

### Regulatory Timelines for Brazil



## ABOUT EUROTRIALS

### **Eurotrials' presence in Latin America builds on 15 years of experience in Europe.**

Since starting in Portugal in 1995, Eurotrials has conducted nearly 500 clinical studies. Opening a Latin American headquarters in Brazil in 2001 was a natural way for Eurotrials to serve clients who needed clinical data from both Europe and Latin America. United by a common language, the staffs in Brazil and Portugal work hand in hand.

From the Brazilian office in Sao Palo, Eurotrials has managed trials throughout Latin America and built unparalleled relationships with the Latin regulatory authorities. But no matter the location, each study is conducted with the highest levels of integrity, quality and ethics that Sponsors have come to expect from Eurotrials.