Challenges of emerging countries: A relatively positive view for the future

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The political-economic world is gradually changing as the world powers give way to emerging countries, or more exactly, to the influence of the corporations. Why are the so-called BRIC countries (Brazil, Russia, India and China) nations that have very large land masses or, rather, very large populations (over 40% of the world population)? Today it is not so much the power of the weaponry of a country that makes it a world leader but the power of the economy, the combined spending power of the inhabitants.

Scientific production should mirror the size of the population as, theoretically, the larger the population, the more people capable of doing research. If 1% of any population is intelligent, there are more intelligent people in China than the entire Belgium population at a little under 11 million⁽¹⁾. Of course this is not completely true of emerging countries as years of undernourishment, underinvestment in education and the allied mentality means that although countries are up-and-coming they will require some years before they can take the position of world leaders. Even so, with this transformation process comes many advantages as multinationals, who want to guarantee their future markets, will invest in these markets. Universities and other research institutions should be prepared to take advantage of these opportunities by attracting financial support for research from drugs companies.

For drugs companies there are also many advantages. The first is obviously the cost. As Glickman et al. stated, the cost of a first class medical center in a developing country can be less than one tenth of the cost of a second class establishment in the USA. The authors attribute much of the cost savings to lower salaries⁽²⁾. Moreover, the regulations in developed countries are much tougher and so it is more difficult to carry out research. Regulations in developed countries have become more and more complex with perhaps excessive burdens on investigators as not always empirical studies are performed to determine which elements improve the conduct in research and which only increase costs.

Large populations provide researchers with great opportunities in terms of the number of eligible subjects making patient enrollment faster. According to Bansal, 83% of US clinical studies fail to recruit the required number of participants within the given timeframe; enrollment in developing countries can be between five and ten times faster than in the US⁽³⁾. Additionally, the number of patients with untreated or undertreated diseases can be a great advantage in researching new therapies although some would argue that the results cannot be generalized to treated populations whose diseases are refractory to treatment⁽⁴⁾.

However there are disadvantages as well. Science in developing countries tends to be of a poorer standard. Moreover, for some authors the socioeconomic differences and disparity in healthcare provided between developing countries and developed countries is a disadvantage - a disadvantage for the developed countries, of course. However, for developing countries it is important to see the true response to treatment regimens in their reality. I believe that many of the poorer results in Brazil for example, are not necessarily due to inability to provide the necessary care for patients, but due to the fact that our reality is different.

Glickman et al. correctly affirm that the genetic makeup of trial populations is very important for the results. Different genetic profiles are related to the safety and effectiveness of drugs⁽²⁾. Thus trials performed solely in the USA cannot be directly translated to a country with such a mixed population as Brazil. It is also worth remembering that, with the size of the population, it may be more worthwhile for drugs to be authorized in developing countries than in the developed countries - in the past, few patients could pay for drugs but recently the buying power of the populations in these countries has been increasing. Population size alone offers the promise of expanding markets⁽⁵⁾.

Ethical considerations are another major concern in developing countries for several reasons not least the lack of education of participants who may not understand the nature of research and the principle behind placebo controls for example. Additionally, the financial reward for participation may be significant compared to the salaries of research subjects and of course there is the lack of reviewing by ethics committees etc..

But how should Brazilian researchers and universities prepare for this future. The first thing we should be doing is to really invest in our participation in international trials. By participating, researchers are not only becoming better known internationally but are also gaining valuable experience. It is important that research in Brazil reaches the international standards required for drugs to be authorized by the Food and Drugs Administration (FDA) and the European Medicines Agency (EMEA).

Today Brazilian research is fragmented with little cooperation even within the same institution. If we are to become a leader in research and scientific production, we must overcome our traditional rivalry and start to work together by sharing ideas, facilities and experience. Departments specifically for research need to be created with all the professionals necessary for good research including laboratory assistants, biochemists, biologists, statistician etc. with weekly meetings to discuss new ideas, problems and the such like.

We need to be more creative in our research projects. The subject matter of most research in Brazil is either dictated by western countries as part of international trials or copies of studies that were performed in other countries in an attempt to validate the data in our population. But there are great gaps in research in less developed countries where the needs are different. One example of this is that among US-sponsored phase III trials

examined by Glickman et al., none were trials of diseases, such as tuberculosis, that are common in less developed countries but rare in the USA.

The state of research in Brazil has changed and continues to do so, but we still have a long way to go before we can truly say that we are a world leader.

References

- Population Chiffres 1990-2011, Service Public Fédéral Belge. [cited 2012 May 10] Available from: http://statbel.fgov.be/fr/modules/publications/statistiques/population/population_-_chiffres_population_1990-2011.jsp
- Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, et al. Ethical and Scientific Implications of the Globalization of Clinical Research. N Engl J Med. 2009;360(8):816-23. Comment in: N Engl J Med. 2009;360(26):2792; author reply 2793. N Engl J Med. 2009;360(26):2793; author reply 2793.
- Bansal N. The opportunities and challenges in conducting clinical trials globally. Clin Res Regul Aff. 2012;29(1):9-14.
- 4. Ibia E, Binkowitz B, Saillot JL, Talerico S, Koerner C, Ferreira I, et al. Ethical considerations in industry-sponsored Multiregional clinical trials. Pharm Stat. 2010;9(3):230-41
- Katz R, Kornblet S, Arnold G, Lief E, Fischer JE. Defining Health Diplomacy: Changing Demands in the Era of Globalization. Milbank Q. 2011;89(3):503-23.