

BRIC Clinical Trial Report: Clinical Trials: Opportunities and Challenges



Introduction

India is primed to become a hub for clinical research and clinical outsourcing activities. In a recent global study by Pharma IQ entitled “*BRIC Clinical Trials: Opportunities and Challenges*”, over half of the survey participants 53.5 % identified India as the BRIC country with the greatest opportunities for clinical trials.

With higher attrition of potential candidates in various phases of drug development and a lack of new drugs, the global clinical trials landscape has changed in recent years. As accessibility, visibility and data quality have increased in the BRIC nations, conducting carrying out clinical trials in Brazil, China, India and Russia has become a much more attractive global proposition. The large patient pools being cited by the survey respondents as the main reason for investing and outsourcing clinical activities to these regions.

The globalisation of clinical research outsourcing has become a key way to improve clinical efficiency and the market for such services developing quickly especially in the BRIC countries.

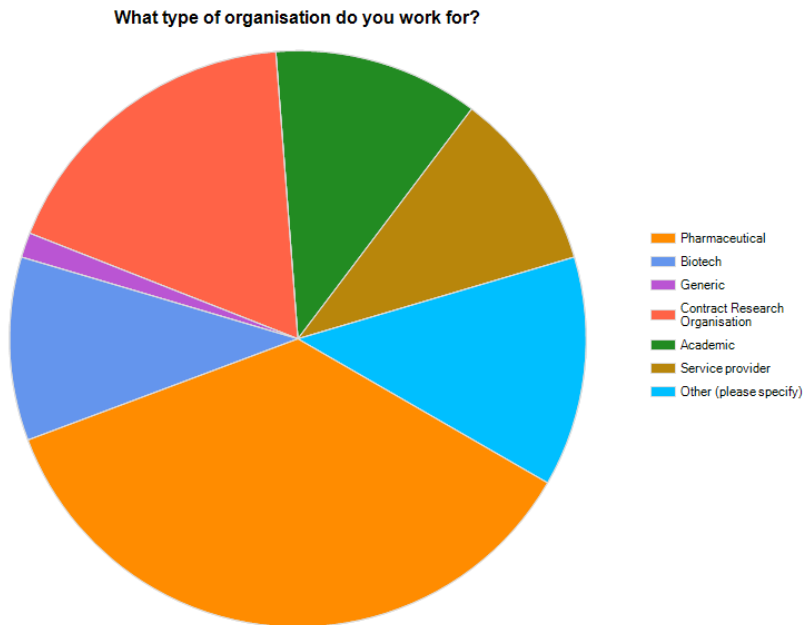
However challenges still remain and many pharmaceutical companies are hesitant to move to these emerging regions. The potential cost and time savings to be gained by conducting clinical trials in BRIC countries can be cancelled out if local regulations and import and export issues are factored into clinical logistics.

Adherence to global standards was also cited by survey respondents as the main challenge for companies looking to conduct trials.

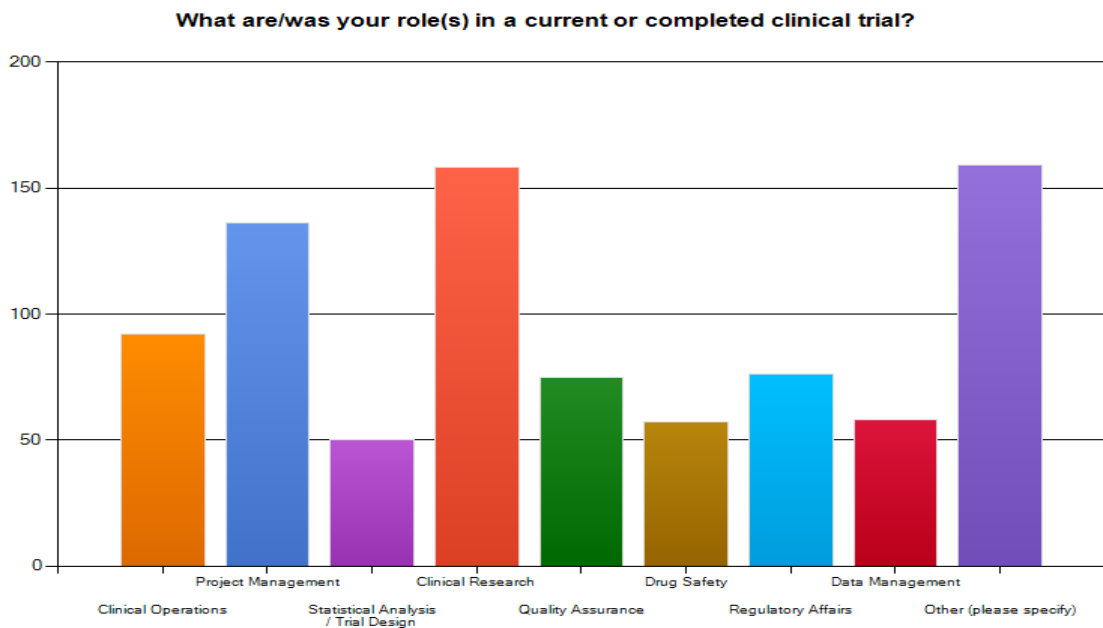
In this report we explore the opportunities and challenges BRIC counties currently present for the global clinical trials market.

About the survey

Pharma IQ surveyed 573 members from the clinical trials community. Over a third of responses were professionals from pharmaceutical organisations, while 10.3% of those involved represented biotech firms. 17.8% were involved with a Contract Research Organisation (CRO). The purpose of the survey was to bring to light the challenges and opportunities the BRIC countries present for the global clinical trials market.



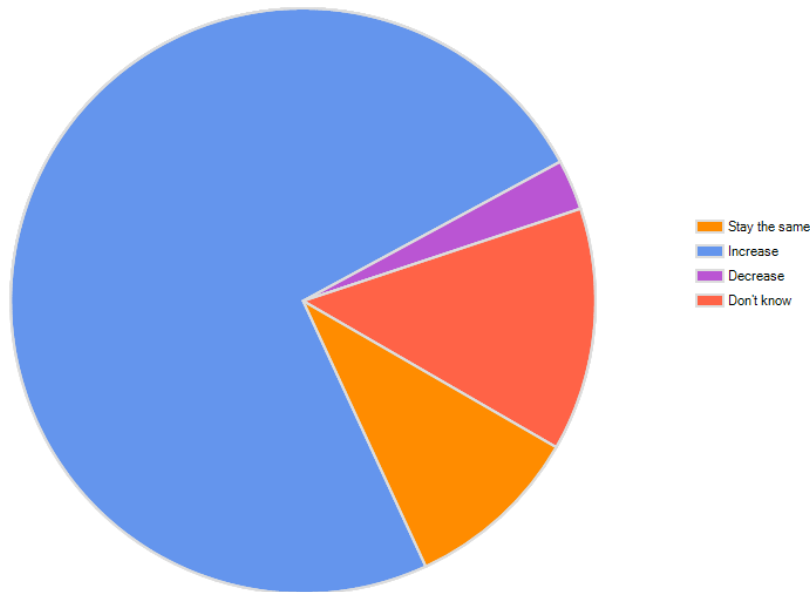
Respondents came from a variety of roles within the clinical trials community, with 27.6% from clinical research, 23.75% project management, 16.1% clinical operations, 13.3% regulatory affairs, 13.1% from quality assurance and the remaining percentage coming from a range of other job functions.



Positive outlook for BRIC clinical trials in 2012

According to the survey the majority of respondents 74% expected the number of clinical trials in the BRIC countries to increase over the next 12 months, with 9.8% expecting them to stay at the same level and only 2.8% expecting them to decrease.

Do you expect the number of trials in BRIC countries in the next 12 months to...



In a recent interview for Data Collection and Management in Clinical Trials Asia, event speaker Bruce Xue, Biostatistical Manager, Medical Affairs Department, Xian-Janssen Pharmaceutical to Pharma IQ: "I do expect there will be more trials in BRIC countries since most pharmaceutical companies are aware of the opportunities for them to grow their business in these countries."

Asia's large patient pools attract clinical researchers

One of the most frequently cited opportunities the BRIC countries offer is their large patient pools.

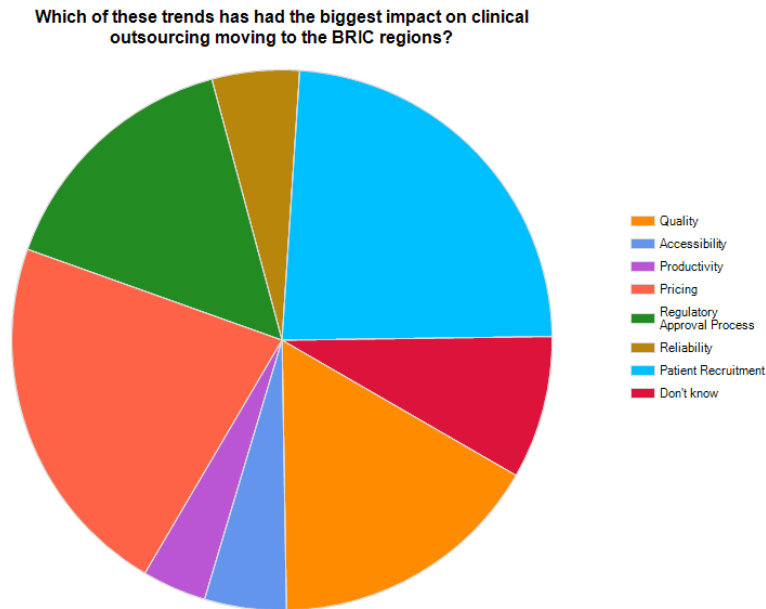
Asia is widely touted as being the rising star of the pharmaceutical industry. Large patient pools, lower costs and rapidly developing expertise make it a key location for research and development, while the large populations present a huge market opportunity.

In a report by Cutting Edge Information, entitled Emerging Markets Clinical Trials: Asia, Adam Bianchi, chief operating officer at Cutting Edge Information, noted: "Drug companies are looking at BRIC and other countries for access to approximately three billion potential new clinical trial volunteers.

"That's several times the medically eligible patient population in established markets," he said.

Patient recruitment and cost-containment measures drive clinical outsourcing

Pharma IQ asked the survey participants which trends had had the biggest impact on clinical outsourcing moving to the BRIC regions, with nearly a quarter citing patient recruitment 23.7%, followed by pricing 22.0% and quality at 16.4%.



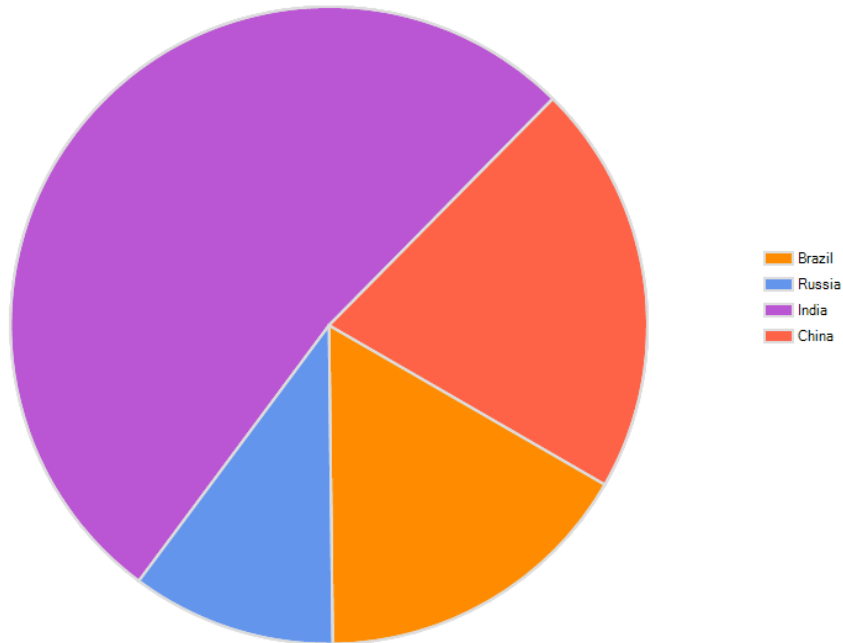
Mark Walls, Director of Clinical Pharmacy at Human Genome Sciences, said to Pharma IQ: "I think with the amount to pharmaceutical companies holding clinical trials in the US, it has just become inundated with trying to find the patients for your trials, or being able to find a specific population and the emerging markets have becoming very popular recently because there are potential cost advantages or there are patient populations that are not available in the US or Europe."

Although figures differ, it is estimated that per patient costs could be cut by as much as 60 percent for clinical trials held in India and China, which conveniently are also among the most populous countries in the world.

India open for opportunity

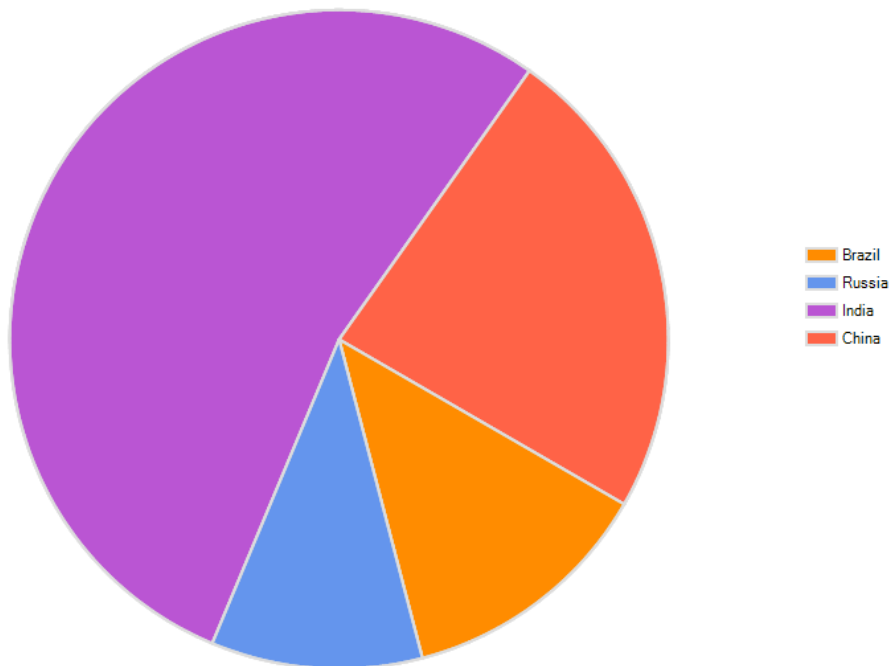
India is one of the hottest and favoured destinations for clinical research outsourcing and conducting global trials. As part of the study Pharma IQ asked participants to reveal which BRIC country they were prioritising for their own business. India was the clear frontrunner with over half the respondents choosing the country. The remaining respondents identified China 20.9%, Brazil 16.5% and Russia 10.4% respectively.

Which BRIC country are you prioritising for your own business?



This is not surprising seeing as 53.5 of the survey participants choose India as the BRIC country with the greatest opportunities for clinical trials followed by China with 23.5%, Brazil 12.6% and Russia 10.4%

Which BRIC country do you think offers the greatest opportunity for clinical trials?



According to the RNCOS report entitled “The Booming Clinical Trials Market in India”, interest in India can be linked to several issues. The country has a large patient pool with both chronic and infectious diseases, meaning recruitment for trials is theoretically easier than in other areas. In addition, the operation of trials is possible at a lower cost.

"Moreover, the changing regulatory environment and introduction of a patent regime has also given a significant boost to the Indian clinical trial market," the report added.

The country also has other benefits such as high levels of qualified English speaking personnel, which may not always be available in other high potential emerging countries.

In an interview with Pharma IQ Dr. Rajendra Jani, Senior Vice President at Zydus Cadila, told Pharma IQ what he thought were the key seven attributes drawing pharmaceutical companies to India to conduct clinical trials, he said: “The list could be exhaustive, but growth drivers are 1. qualified English speaking manpower, 2. global medical practices, 3. medical infrastructure, 4. diverse, treatment naïve patient pool, 5. globally acceptable regulatory environment, consistent high quality and on time delivery.”

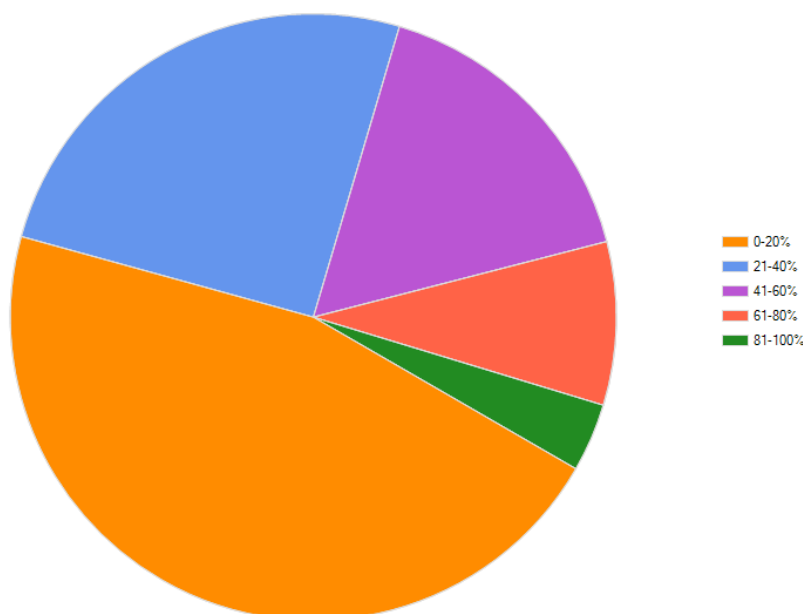
Hesitant BRIC entry

Faced with a global economic cut backs and a Eurozone crisis, pharmaceutical and biotech organisations are investing further in emerging markets, but there is still some hesitation with regards to the challenges they present.

Steven Jacobs, President, Global BioPharm Solutions, LLC, Chair Global Clinical Supplies Group, Inc. said to Pharma IQ “The BRIC countries studies are one of the most amazing things that I have ever seen and the reason for that is that they are the epitome of the pendulum, so I see certain companies really leveraging those opportunities but other companies talk about it, but don’t really do it.”

Although they saw great promise in the BRIC regions, 46% of survey respondents only ran 0 – 20 % of their clinical trials in Brazil, Russia, India and China. Just over a quarter ran 21 – 40 % in the BRIC countries and just 3.6% ran over 81 % of their clinical trials in a BRIC country.

What percent of your clinical trials are being run in these regions?



As the emerging markets become more favourable destinations for conducting clinical trials, the challenges faced by clinical trial management become more complex, with challenges such as cultural barriers, understanding local regulations, importation and exportation guidelines and obtaining of licenses.

Mark Walls, Director of Clinical Pharmacy at Human Genome, said to Pharma IQ: "In addition to all the positives of carrying trials out in emerging markets, some hurdles that companies would face include cultural differences, one of the big differences is time differences, there could be some language barriers, you could potentially have some lack experience, import export challenges, training in your area, exporting the product."

Dealing with electronic data capture, you could also have issues with phone and internet access," he added.

Global standardisation vs. local regulation

Pharma IQ asked the survey participants to pinpoint the main challenge for running clinical trials in BRIC countries.

Adherence to global standards was cited as the number one response with nearly a third of participants, 32.2%. Pharmaceutical companies must assume responsibility for their product quality and safety and therefore need to ensure that the companies they work with globally comply with not only local but also globally recognised standards.

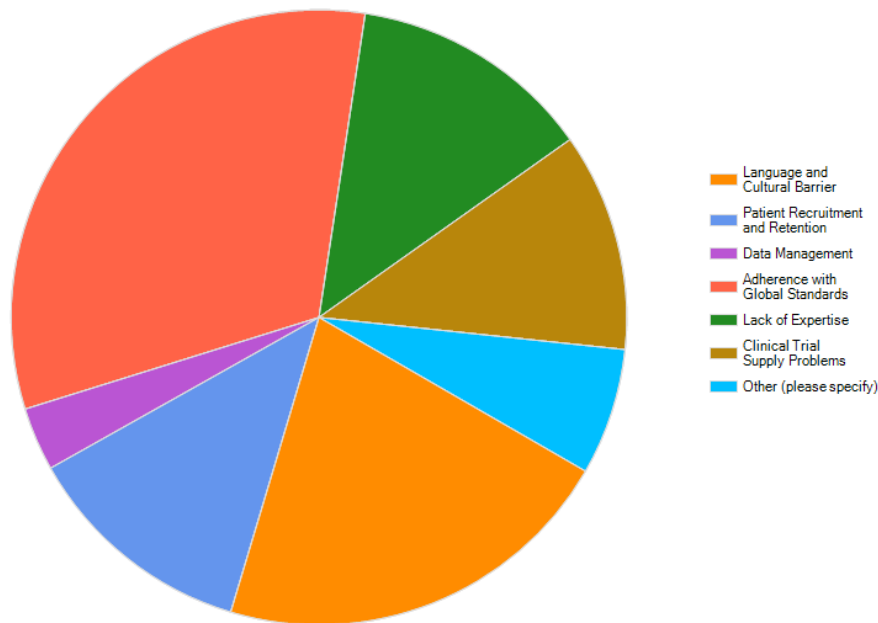
The benefits and efficiencies of standardising clinical trial design can be outweighed when trials are conducted in a global environment.

At Pharma IQ's Clinical Trial Supply Conference, Alfredo D'Addio Strategic Planner, Global Investigational Material Supply Chain, Celgene Corporation, said: "A lot of the trials are becoming similar in design, so it is very efficient if there is some sort of standardisation, therefore you are not trying to reinvent the wheel every time. The benefits are you have one set of supplies that can be used globally, some of the challenges with that though are the regulations, you will have different regulation requirements for each country and they change."

With patient information being sent to clinical study sites across the globe, the industry is seeking to address challenges like clinical data security: "Through security enabled IT technology, strong standard operating procedures and promotion of ethics in practice," said Jani.

Other survey respondents identified the main challenge as language and cultural barriers at 21.3%, lack of expertise at 12.8%, patient recruitment and retention at 12.2% and clinical trial problems at 11.5%.

What do you think is the main challenge for running clinical trials in the country you selected?



Clinical trial supply management can make or break a clinical trial.

Getting the clinical logistics right is crucial to the success of a clinical trial and it is paramount that regulatory requirements are fully understood and processes are in place to ensure seamless supply and distribution of clinical materials, so that clinical trial timelines are not comprised.

Mukesh Kumar, President of the Global Alliances of Indian Biomedical Professionals told Pharma IQ: “Logistics is a bigger issue when including emerging countries. Once the logistics are taken care of, it becomes relatively easy to execute... You can’t have too many variables. So either you plan for the number of patients and an out and out amount of drug for the number of sites, but if you do too many variables, it becomes more and more logistically hard to manage those trials.”

“Try to plan in such a way that they can predict much better how much of each of the logistical issues they would need to address when including any of these countries. Once those are addressed, everything else becomes easier,” Kumar added.

For many stakeholders in the clinical trial supply arena supporting the expansion of clinical trials into emerging markets and new therapeutic areas is a key priority.

Ray Goff Director, Vaccine Production Pfizer, spoke to Pharma IQ about increased time spent implementing a clinical supply in the BRIC countries: “What we are finding is going to those countries takes more time just right now, especially Russia and the Ukraine,” he said.

If pharmaceutical and biotech companies don’t want to lose quality when accelerating clinical trials it is important they remain aware of global standards among all stakeholders along the clinical supply chain. This requires more stringent monitoring and quality assurance activities, when quality cannot be assured the result is additional cost.

“In Brazil we are being asked to ensure that everything is monitored and that there is proof of monitoring. In the area of cool chain that’s going to require a little more diligence from us and

we are seeing the timeline going much longer and any of the customs or logistics challenges need to be dialled into to all your estimates for supplies. At the same respect if that doesn't happen, you may end up getting more excursions which will require more supplies from you," Goff said.

Pharmaceutical companies are also looking for ways to cut overages and saving money by successfully adopting S&OP processes drawn from commercial supply into a clinical setting.

Alex Klim, product manager for DHL Supply Chain's Clinical Trials Logistics Service (CTL), said to Pharmaceutical Manufacturing and Packing Sourcer: "In the BRIC territories the cost of not having drugs available for a patient once recruited is often countered by oversupplying; it is not unusual to have an overage of supply of about 280 per cent as a lot of the drug is put into each country to ensure there is no chance of not having the right drug when the patient turns up. As a result, tax and duty costs will be high but, more significantly, since they often have short shelf lives due to limited stability data, write-offs will not just include the production value of the drug and logistics cost, but also wasted tax and duty charges."

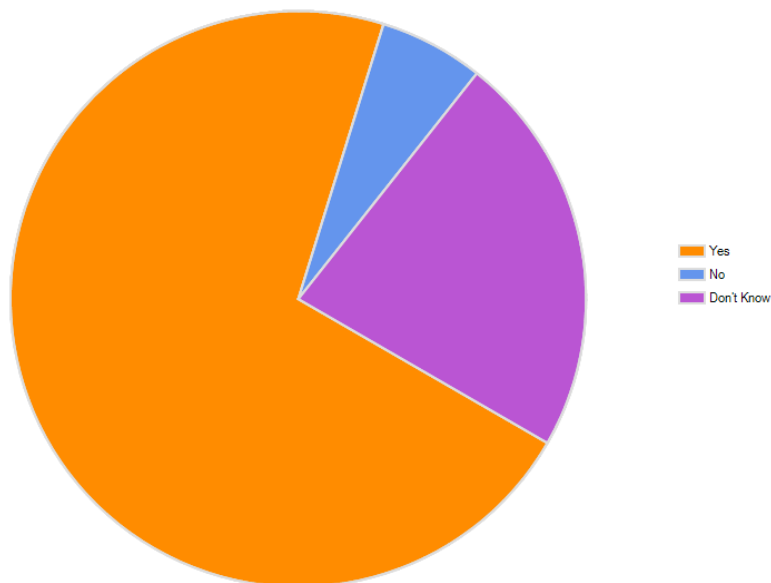
BRIC solid investment

Despite these challenges the number of clinical trials being conducted in BRIC counties looks set to grow.

Walls remarked: "I think they are growing more and more, you see more CROs. As more companies go to the emerging markets CROs offer more services."

Over 70% of the survey participants thought that the BRIC countries were a solid investment for clinical trials, under 6% of respondents did not.

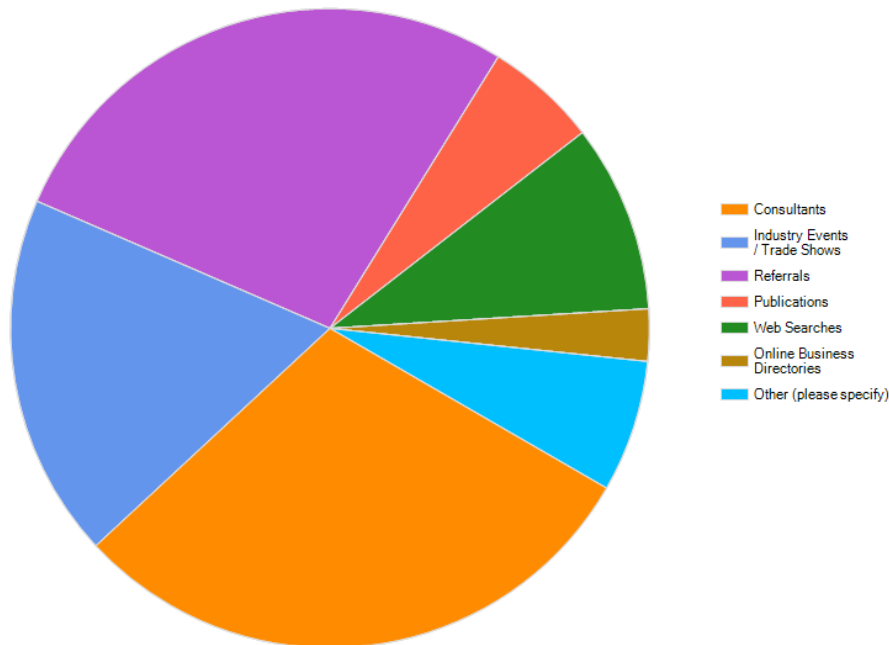
Are BRICs a solid investment for clinical research?



So how do you choose a partner?

The participants were asked how they select the right outsourcing partner to reach their clinical research objectives. Unsurprisingly 29.8% used consultants, 27.3% referrals and 18.4% selected their clinical outsourcing partner at industry events and trade shows. Very few respondents relied upon independent research on online business directories.

How do you select your outsourcing partners?



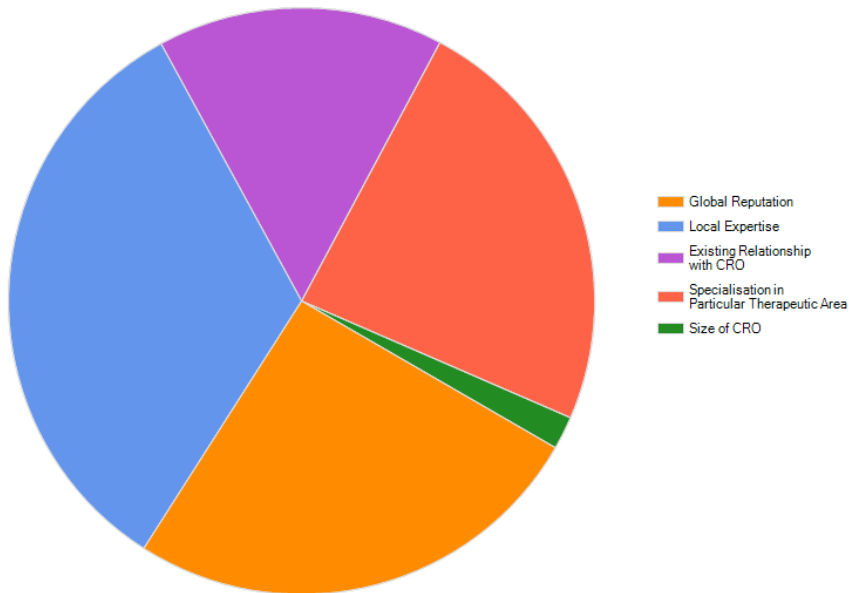
Creating strategic partnerships

Selecting the right CRO for your company and product is of paramount importance. The time taken in technology transfer means that you could wipe up to 5 years of your pipeline development if you get it wrong.

As a result, we are starting to see a greater shift towards collaboration and shared risk in clinical development. The relationship between CRO and sponsor has become much more strategic to increase clinical efficiency and help foster innovation.

Pharma asked the survey participants specifically about their selection criteria for choosing a CRO to work with in Brazil, Russia, India or China. Local expertise proved to be most important at 33%, closely followed by global reputation 25.7% and specialisation in a particular therapeutic area 23.7%. For 15.8% an existing relationship with a CRO was of the upmost importance. The actual size of the CRO did not appear to be an important factor for most participants with just 1.8%.

What is the most important criteria when choosing a CRO in BRIC countries?



Unlocking potential

To ensure the greatest ROI and an effective CRO-sponsor partnership, pharmaceutical companies must also improve their own processes.

“Every sponsor company has got to work on their processes their personnel, their training their team work and once again their trust building in order to leverage the countries we are all going to now and then they can really focus on making the BRIC countries a wonderful resource for continued research and development,” said Jacobs.

If pharmaceutical companies can embrace both the challenges and opportunities of working with BRIC countries and are prepared for some internal change they will be able to unlock their true potential.

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