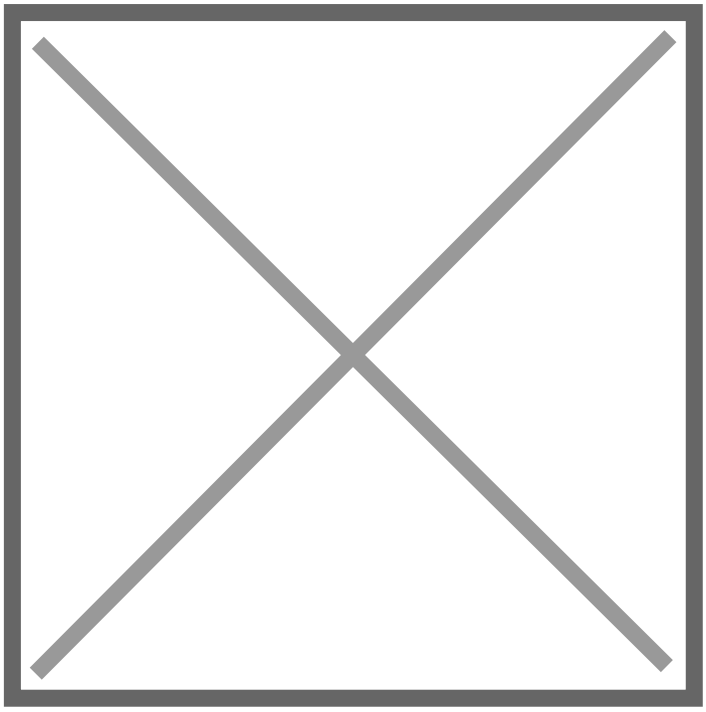


CRO hotspots

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India confident to dominate

Teamworkshutterstock1273502**47%** serve sponsors with a revenue range of more than $200 mn

30% focus on client expansion; 28% on revenue growth as key priorities

76% confident about increasing opportunities over next three years

- Most enterprises operating in India are small and medium-sized
- Average contract size for CROs in India is under $50 million
- Top therapeutic focus areas are oncology, cardiovascular diseases, CNS, respiratory diseases and dermatology
- India, China, South Korea are hotspots for patient recruitment and trials
- Indian CROs are concentrated on contract and clinical research
- Quality, reliability, regulatory compliance, pricing, productivity and accessibility are key performance metrics

With an obective to capture the key trends of the pharmceutical CROs in the region, BioSpectrum, in association with CyberMedia Research (CMR), a premiere market research firm that specializes in competitive intelligence, advisory and consulting for life sciences and healthcare, primarily in the APAC region, conducted a survey to identify the latest trends and issues facing the pharmaceutical contract and clinical research industry.

FOURTH ANNUAL *BIOSPECTRUM* - CMR SURVEY OF THE CONTRACT AND CLINICAL RESEARCH ORGANIZATIONS (CROS) 2012

This report by BioSpectrum and CMR is based on a survey of 18 senior CRO executives from India.

All the respondents were from the C-level, or above, and based in India. Respondents came from companies of all revenue sizes, with 93 percent representing CROs with less than $50 million in annual revenues, while seven percent from companies in excess of $500 million.

The survey included a mix of quantitative and qualitative research, administered through email, and direct telephonic interviews with senior executives and experts in India. In addition, desk research was conducted to complement the survey findings.

Indian CROs in the Asia-Pacific CRO Ecosystem

Indian CROs are slowly expanding their geographical reach by focusing on multiple geographies to cater to their global clientele. According to 32 percent of the respondents of the Fourth BioSpectrum-CMR Annual Survey of the Clinical and Contract Research Organizations 2012, India is their key focus market wherein all their services are concentrated. Fourteen percent of the CROs have a presence in Malaysia, while 11 percent are focused on China. These are the top three countries of Asia-Pacific wherein Indian CROs are focused on providing their services. Interestingly, Australia, South Korea, Singapore, Japan, and Taiwan are also geographies wherein Indian CROs have expanded their reach.

Graph1

Biospectrumcmrslug1

Asia-Pacific hotspots for clinical trials and patient recruitment

Unlike the West, Asia-Pacific has been a fertile ground for patient recruitment, with the willingness to participate by patients being traditionally high. This can be traced to the large available patient population. In addition, the lifestyle and stress-related diseases such as diabetes and cardiovascular diseases are increasing rapidly among the Asian population, owing to increasing adaptation of sedentary lifestyle. When compared to the West, the number of available patients is also higher at each trial site as they are located at large hospitals.

According to the survey respondents of the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012, China and South Korea (18 percent) and India (28 percent) with their vast population are the key countries wherein the willingness to participate in clinical trials is high. The willingness to participate is also high in countries such as Malaysia, Thailand and Singapore.

Graph2

A snapshot of Indian CROs

According to the survey respondents of the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012, Indian CROs are engaged in both clinical and contract research. 45 percent of Indian CROs are focused on contract research, while 41 percent are engaged in clinical research.

According to 14 percent of the Indian CRO survey respondents, they are engaged in biomanufacturing. Early trends indicate that India and China are seeing increase in contract manufacturing.

Graph3

Services offered by CROs

The Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012 reveals that CROs in India offer a wide array of services. According to 77 percent of the survey respondents, their services are concentrated around project management, clinical trial monitoring, quality assurance and medical writing.

72 percent of the CROs offer patient and investigator recruitment and site management, while 66 percent of the CROs provide trials, regulatory affairs and data management. 61 percent of the CROs provide biostatistics and medical scientific services. 55 percent, 50 percent, and 38 percent of the CROs offer drug safety, pharmacovigilance and bioanalytical laboratory services respectively.

Graph4

The concentration of clinical trials by phase

According to the survey respondents of the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012, Indian CROs are focused across the preclinical, phase I to phase IV pathway. According to 22 percent of the respondents, phase II and phase III are where the clinical trials are most concentrated. Nineteen percent of the respondents cited that their clinical trials are mostly in the preclinical Phase while 17 percent indicated phase IV.

Graph5

93 percent of CROs continue to operate within a revenue size of $50 million

According to 93 percent of the survey respondents of the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012, they operate below the $50 million band.

Seven percent of the companies indicated a revenue size greater than $500 million.

Graph6

Oncology is the hottest therapeutic area for Indian CROs

Oncology is the top therapeutic focus area for Indian CROs, with 63 percent of the respondents of the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012 citing it.

Indian CROs are focused on an array of therapeutic research areas including metabolic diseases, infectious diseases, pain management, hematology, anti infectives, rheumatology, inflammation, and ophthalmology.

Graph7

21 percent of the CROs serve more than 50 clients every year

According to the survey results of the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012, 21 percent of the Indian CROs serve more than 50 clients every year.

Graph8

Average contract size of Indian CROs

As per the survey results of the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2011, over 90 percent of the Indian CROs operating in the Asia-Pacific region have an average contract size of worth $1-5 mn with each customer.

47% of the sponsors are in $ 200 million revenue range

According to 47 percent of the respondents of the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012, Indian CROs serve sponsors with a revenue range greater than $200 million. 15 percent of the survey respondents indicated that the revenue range of sponsors is less than $50 million, while another 23 percent serviced sponsors with a revenue range in the than $101-200 million bracket.

Graph9

Key performance metrics for Indian CROs

Measuring and tracking performance related to study conduct at all stages of the clinical trial lifecycle has been given prime importance by CROs with the intentention to implement cohesive strategies for improved efficiency and quality in clinical trials. According to the respondents of the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012, quality (18 percent) is the most important parameter for measuring their performance, followed by reliability (14 percent), regulatory compliance (14 percent), pricing (13 percent), productivity (12 percent) and accessibility (10 percent).

Graph10

Number of employees

Indian CROs are small to mid-sized operations. According to 27 percent of the respondents to the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012, they employ around 251 to 500 personnel, while 16 percent indicated that they have 101 to 250 personnel.

22 percent of the respondents indicated that they have 51 to 100 personnel, engaged in various functions.

Graph11

Functional roles in a CRO

The Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012 reveals that 50 percent of the employees in an Indian CRO perform the role of Clinical research associates, seven percent of the workforce manage database management while 21 percent of the workforce comprises of the sales, management and administration.

Graph12

Most important priorities for Indian CROs

Indian CROs are focused on revenues and client expansion as their key priorities, while looking to expand geographically. According to 30 percent of the respondents of the Fourth *BioSpectrum*-CMR Annual Survey of the Clinical and Contract Research Organizations 2012, client expansion is the most important priority for their enterprise.

Revenue growth is the key priority for 28 percent of the survey respondents, while according to 21 percent of the survey respondents, geographical expansion is the most important priority. These trends are in line with the trends captured in the previous *BioSpectrum*-CMR surveys. According to 21 percent of the Indian CROs surveyed in the *BioSpectrum-CMR Asia-Pacific Annual Survey of the Clinical and Contract Research Organizations Survey 2012, product development is the most important priority for them.*

Graph13

According to the Indian CROs, the rich experience and expertise of the CROs in India, the increasing research and development investment by biopharma in strategic collaborations, and cost pressures encouraging R&D outsourcing are some of the factors influencing their optimism in increasing market opportunities.