

Asia Pacific CRO Survey 2011

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Over the past two years, BioSpectrum Asia has been capturing the key trends in pharmaceutical, clinical and contract research (CRO) organizations in the Asia Pacific region through focused annual industry surveys. For this 3rd Annual CRO Survey, we partnered with CyberMedia Research (CMR), a premier market research firm that specializes in competitive intelligence, advisory and consulting for life sciences, healthcare and IT enterprises, primarily in the APAC region.



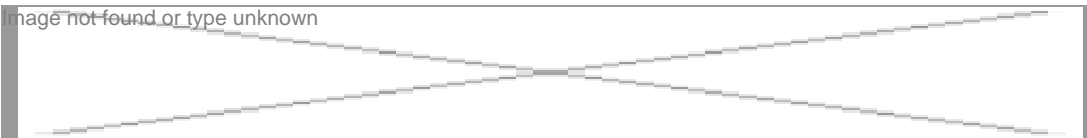
The BioSpectrum-CMR Asia Pacific Clinical and Contract Research Organizations Survey 2011 points to radical changes to the business model and strategy for outsourcing firms, and to an exciting phase of growth ahead. The outlook for the outsourcing industry is optimistic, with R&D spending being the key variable. The level of outsourcing is set to increase, and strategic partnerships are likely to overshadow the transactional project-to-project approach that has been the norm. In the following pages, we present the results of the 3rd Annual CRO Survey.

Highlights

- Sixty-six percent of our survey respondents operate in the full service CRO category, while 34 percent are in the niche category.
- The average contract size for CROs in Asia-Pacific is \$8.5 million. Most of the enterprises operating in the APAC

region are small and medium-sized.

- The top five therapeutic areas of focus for CROs include oncology, cardiovascular diseases, dermatology, neurology and respiratory. This is in line with the trends depicted in the earlier Annual CRO Survey that pointed out that oncology is the hottest therapeutic area focus for CROs.
- According to the survey respondents, India and China are the hotspots for patient recruitment and clinical trials.
- In the APAC region, the concentration of clinical trials is most in phase III. There are some niche CROs operating in other phase I and preclinical research, and some CROs that span across the developmental pipeline.
- The top priority for 47 percent of the survey respondents is client expansion. This is followed by revenue growth, product development and geographic expansion.
- Thirty-four percent of the respondents indicated that the revenue of the sponsors is in \$101-200 mn range. A majority of the mid and small sponsors originate from APAC region, and predominantly from India.
- According to the survey respondents in the sponsor category, over the next three years, the outsourcing budget is likely to increase.
- When assessing a CRO/CMO, the primary and key strategic consideration is quality and reliability. This takes precedence over other critical factors such as pricing, regulatory compliance and productivity.



Survey Methodology

The survey included a mix of quantitative and qualitative research, administered through email and direct telephonic interviews.

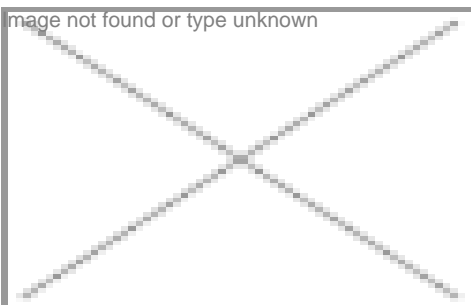
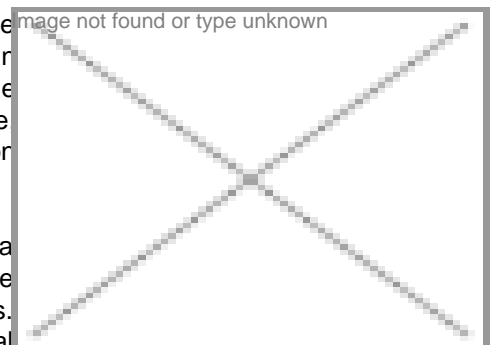
The scope of the survey includes multinational, regional and local CROs based in the Asia Pacific region with revenues upto \$1 billion. For the first time in our annual survey, we have expanded our scope to include the perspective of the sponsors. The survey includes biopharmaceutical enterprises in the large, mid and small categories.

Our survey gathered data from 422 respondents spread across large, regional and small firms in the CRO/CMO industry, and 90 respondents from the biopharma industry. We received responses from 37 respondents in the CRO industry. The survey respondents came from diverse geographies including, India, China, Malaysia, Singapore, Taiwan, South Korea, Australia, Ireland, Scotland and North America.

Focus Areas for CROs

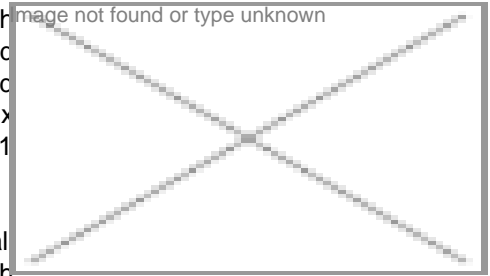
According to the 3rd BioSpectrum-CMR Asia Pacific Clinical and Contract Research Organizations Survey 2011, 36 percent of the respondents are engaged in both clinical and contract research. Thirty percent of the respondents indicated that they are into clinical research, while another 30 percent focused exclusively on contract research. Four percent of the respondents are engaged in contract manufacturing.

Some CROs are operating as a one-stop shop, servicing a full range of early-to-late stage clinical development projects for their clientele. To differentiate themselves in the crowded market, some of the CROs have developed niche skill sets. Some CROs operate their business through dedicated units that focus on early phase phase II-III, late phase business units, and also, business units that focus on technical, pharmaceuticals and medical devices business.



Most of the clinical trials in the Asia Pacific region are concentrated in phase II, phase III and phase IV trials. Significantly, phase I and preclinical segments are also witnessing some activity. According to 19 percent of the respondents of the Survey 2011, phase III is where the clinical trials are most concentrated. Phase II was cited by 18 percent of the respondents, while phase IV was cited by 15 percent of the respondents. According to 16 percent of the respondents, their clinical work is centered around preclinical research, while another 10 percent have most of their clinical research activity in phase I trials.

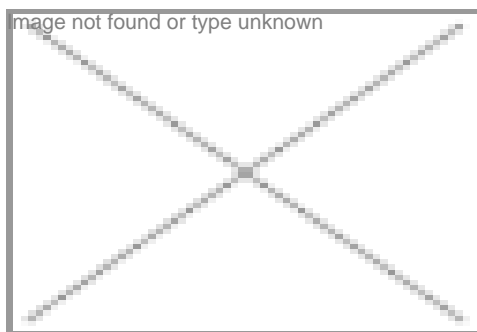
Over 81 percent of the CROs operating in Asia Pacific have received orders worth \$1-10 mn. Ten percent of the survey respondents indicated that they have received orders in the \$11-25 mn range, while three percent of respondents have indicated that the contract size received by them is in the \$26-50 mn range. Interestingly, six percent of our survey respondents indicated that they receive contracts in the \$101-200 mn category.



However, Asia Pacific is home to mostly small and medium-sized CROs with small dedicated resources, as indicated by 81 percent of the respondents. For such CROs, it is tough to take up big orders. The lack of resources acts as a hindrance when one considers big orders above \$50 mn.

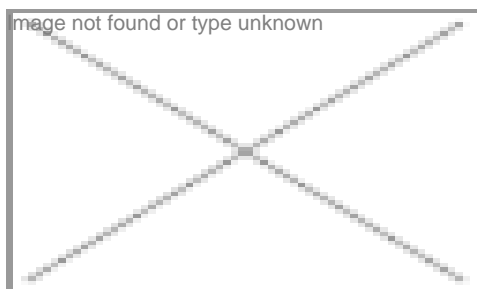
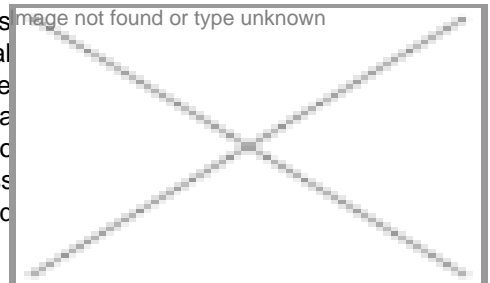
Market Opportunity Assessment

Eighty-three percent of the respondents of the BioSpectrum-CMR Asia Pacific Clinical and Contract Research Organizations Survey 2011 indicated that the market opportunities would increase for full-service and niche operators, while 11 percent of the respondents opined that the market opportunities would remain the same. Surprisingly, six percent felt that the market opportunities would decrease over the next three years.



The survey respondents indicated many different factors for their assessment and confidence in increased market opportunities. Some of the key factors that respondents indicated include: current global economic realities, cost pressure for sponsors, growing regulatory burdens, the daunting challenges of operating in the West, marketplace globalization and significant increase in outsourcing levels. Some of our survey respondents indicated that geographical and market expansion

According to one respondent's assessment, the biopharmaceutical industry increasingly recognizes the contribution to global and regional trials across all clinical trial phases by Asia Pacific CROs. The respondent further opined that India and China are expected to be the favored destinations for outsourcing clinical research in Asia and will witness significant growth in the CRO markets. Taiwan, Japan and South Korea are primed for increased CRO activity in conducting phase I-IV clinical trials.



According to one survey respondent, the Indian clinical research market is benefiting from an improving regulatory framework that is supported by a rigorous regulatory oversight. This is attractive for sponsors interested in conducting clinical

To leverage their competitive edge and be successful in the market in the future, both full service and niche CROs need to differentiate their service from others. The key differentiators for successful CROs should include, flexibility, quality, reliability, as geographical spread.

When assessing the key potential trends over the next three years for the APAC market, 36 percent of the respondents indicated an increase in strategic partnerships with biopharma. According to 32 percent of the respondents, business contracts will increase. Eighteen percent of the respondents opined that significant market consolidation will occur and 14 percent indicated that niche CROs would proliferate.

Eighty percent of the survey respondents indicated that the Asia Pacific market will consolidate, while 17 percent of respondents were more cautious and predicted that the market will remain the same. According to three percent of the respondents, the market will fragment.

Measuring CRO Performance

The CROs are optimistic about the opportunities for their strategic growth in the market. Identifying and implementing metrics can help improve and maximize clinical trial performance. Also, metrics provide sponsors with the key they need to work together to run clinical trials efficiently.

So, how does the CRO industry measure itself? What are the most important parameters for measuring performance?

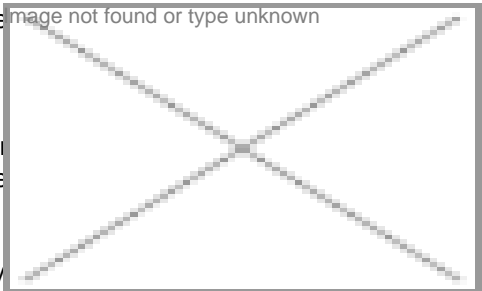
According to BioSpectrum survey respondents, quality (25 percent) is the most important parameter for measuring their performance, followed by reliability (20 percent), regulatory compliance (17 percent) and pricing (15 percent).

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Revenue band

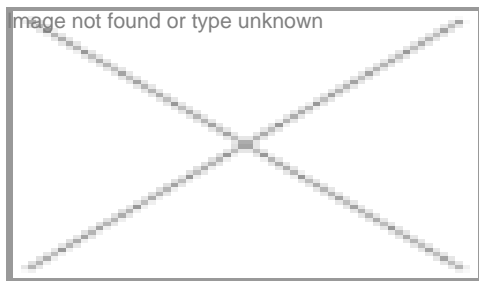
Nineteen percent of the respondents of the BioSpectrum-CMR Asia Pacific Clinical and Contract Research Organizations Survey 2011 indicated that they operate in the revenue band of \$26- 50 mn. An equal percentage of respondents indicated that they operate in the \$16-20m band. Thirteen percent of the respondents operate in the revenue band of \$1-5 mn and \$6-10 mn respectively.

Only 10 percent of the respondents have a revenue size of \$101-500 mn, while another three percent have revenue size greater than \$ 500mn.



Number of Clients

More than 60 percent of the survey respondents indicated that the average number of clients serviced by them per year is less than 15. Less than 10 percent of the survey respondents indicated that they serve more than 100 clients every year.



Some respondents indicated that they have long-term dedicated relationship with clients for the same customers.

In response to a question on the revenue range of the sponsors, 34 percent of our survey respondents indicated that the sponsors are in the \$101-200 mn range. While 24 percent of the survey respondents indicated that the revenue range of sponsors is less than \$50 mn, another 22 percent serviced sponsors with a revenue range greater than \$200 mn. Twenty percent of respondents indicated that sponsors serviced by them were in the \$51-100 mn range.

Key Priorities for CROs

CROs in the Asia Pacific region have benefited tremendously over the past five years from a variety of factors including changing ecosystem, drying pipelines, strategic partnership opportunities with biopharma, diverse therapeutic clinical expertise and vast patient population. As the developed world continues to be enveloped by tough economic conditions, and the product pipelines of pharma enterprises are shrinking up, Asia Pacific CROs are gearing up to increase their presence globally and leverage their competitive advantage.

According to 47 percent of those polled by the BioSpectrum-CMR Asia Pacific Clinical and Contract Research Organizations Survey 2011, client expansion is the most important priority for their enterprise. CROs are working with a diverse set of clientele across geographies including industry, government and academic research institutions. Apart from clients in North America, CROs in the Asia Pacific region are focusing on Europe.

Top five focused therapeutic areas

Therapeutic areas	By percentage (2011)
Oncology	64.50
Cardiovascular diseases	23.33
Dermatology	11.11
Neurology	17.86
Respiratory	15.38

Revenue growth is the key priority for 30 percent of the survey respondents, while according to 11 percent of the survey respondents, geographical expansion is the most important priority. As published last year in the results of the 2nd BioSpectrum Asia Pacific Clinical and Contract Research Organizations Survey 2010, CROs are according development.

According to 12 percent of the respondents, product development is the most important priority. CROs are offering geographical expansion and product development as a value proposition for their global clients

operating from North America and Europe.

Oncology: Top therapeutic area

According to the survey respondents, the top five focused therapeutic specializations include, oncology, cardiovascular diseases, dermatology, neurology, and respiratory.

For biopharma, oncology continues to be a key growth segment and Asia Pacific with its vast patient pool, lower costs and rapidly developing expertise is an attractive destination for the development of their cancer therapies.

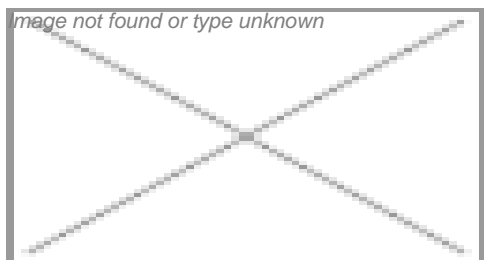
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The expansion within the biosimilars market is also fuelling the growth of clinical trials across Asia, with the Indian market getting primed for introduction of new oncology-based biosimilars in the near future. Much of the clinical research in Asia Pacific is centered on oncology.

According to the results of the survey, other major therapeutic areas of focus for CROs include metabolic diseases, infectious diseases, pain management, hematology, anti infectives, rheumatology, inflammation and ophthalmology.

Patient Recruitment

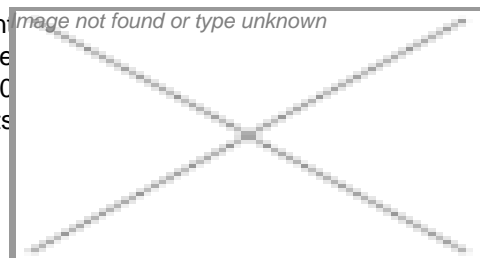
In recent years, a key trend that has emerged is of CROs understanding the increasing size and complexity of clinical trials and addressing one of the most critical bottleneck in drug development – patient recruitment.



According to the survey respondents, China (26 percent) and India (25 percent) with their vast population are the two key countries wherein patient recruitments are happening, followed by Korea with 14 percent, and Taiwan with seven percent. Survey respondents also indicated Singapore, Japan, Australia, Thailand and it patient recruitment is happening.

For volunteers interested in participating in a clinical trial, money is one of the key considerations. The decision to participate in a clinical trial is a complex one. Forty-four percent of our survey respondents indicated that they do pay their volunteers, while 56 percent of the respondents do not pay volunteers.

Among the survey respondents who indicated that volunteers were paid, 30 percent indicated that they pay their volunteers less than \$50. Forty percent of the respondents indicated monetary benefits in the range of \$51-100, while another 20 percent indicated \$101-200 as benefits. Significantly, 10 percent of the respondents pay volunteers upwards of \$500.



Source for all charts: CMR