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ASIA EDITION

APAC is the fastest growing market for CRO industry

02 June 2017 | Opinion

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“The CRO market in APAC, the fastest growing region in the world, has been increasing at a CAGR of 19.5 percent,” highlights Ms Mary Pan, Vice President of Asia Pacific, ICON in an interaction with BioSpectrum Asia Magazine. Excerpts of the interview-

What are current trends in Asia Pacific - CRO Industry?

Drug lag is the term used to describe the oftensizable delay between the times a new drug is approved in the US or EU compared with that in Japan and China. The drug lag has been approximately 3.5 years for Japan and 5 years for China. As a result, innovative medicines, including those in key therapeutic areas, such as oncology, are taking much longer to reach patients in Japan and China. Both countries have stated an objective to reduce the drug lag, andaiming to reach parity with the US by 2018 and 2020, respectively.

The implications of this are an increase in the number of global clinical trials in the earlier phases (II and III) that will include Japan and China and an increase in pan-Asia Pacific clinical trials. A decrease in regulatory approval timelines means that it is sensible to include Japan and China as a part of a global filing and development strategy rather than performing bridging

studies post NDA in the US or post marketing. An increased willingness to accept data from Asian populations outside Japan means that conducting more pan-Asian studies is a good option to be competitive in terms of filing from a cost and time perspective. Data from the Pharmaceuticals and Medical Devices Agency (PMDA), part of Japan's Ministry of Health, Labor and Welfare (MHLW), indicate that the drug lag was 3.4 years in the financial year 2007 and has fallen steadily to 1.1 years by 2010.

Much of the improvement in drug lag can be attributed to a shorter regulatory review period. Between 2008 and 2011, the average time for standard review decreased by nearly 50%, reflecting a drop from 22.0 months to 11.5 months. The gain was even more impressive for priority reviews, which had an average cycle time of 15.4 months in 2008 but only 6.5 months in 2011. Preliminary data from 2012 indicate that the review periods continue to decrease and will easily meet the government's targets (9 months for priority reviews and 12 months for standard reviews). In particular, the 5-year plan contains provisions to reduce review times by hiring additional PMDA personnel (especially physicians) and expanding training and educational programs.

China is learning from its peers in the region and reducing drug lag by hiring more reviewers (37% more in 2015) andimproving processes. China is also implementing a 'four-colour-light' strategy where different drugs are classified into redefined categories of innovative and generic drugs, with priority being given to approval decisions concerning innovative drugs. Since 2014, changes have occurred in the organization and procedural activities of the China Food and Drug Administration (CFDA) and the Center for Drug Evaluation (CDE), impacting participation in multiregional clinical trials (MRCT) and increasing overall regulatory review times.

The lengthy queue time (>5 months) before the review of MRCTCTA applications, coupled with a long review time (approximately 12 months), has caused uncertainty about the timely inclusion of China in MRCTs. The agency has recently taken positive steps, for example, by increasing resources (through the use of recently implemented increases in registration fees) as well as indicating their intention to increase CDE staff numbers to approximately 1,200 by 2020, in order to accelerate the review of the backlog of older (pre-December 2013) submissions over the next 2–3 years. The CFDA/CDE commitment to increase internal staff numbers together with their public commitment to reduce the backlog have the potential to have a positive effect on the dynamic Chinese regulatory environment. China's fast-growing pharmaceutical market has become a significant growth driver for multinational companies, with spending estimated to reach $300 billion by 2020 according to recent article in Bloomberg. If this holds true, China will become the second largest pharmaceutical market in the world, followed only by the US. It should be noted that the reduction in drug lag in China, though very fast moving, was started approximately 2 years ago, while the reduction in drug lag in Japan has been underway for over 6 years.

What are the key factors affecting CRO business in APAC?

For local or domestic country trials, local companies tend to use local CROs and multinational corporations (MNC) tend to use their local teams or insourced personnel. Local CROs cost 20–100% less than global CROs because they have lower overheads (e.g., no requirement to speak English outside management level) and are structurally less complex (local decision making and greater efficiency). MNCs sometimes have agreements with local Economic Development Boards to maintain local teams as a part of an overall development scheme. However, due to unpredictable changes in clinical development status and the resulting volatility in utilisation, higher turnover rates with local teams incentivise management to look to insourcing. The risks associated with fixed assets drives outsourcing penetration.

In your opinion, how will the CRO market perform in the next 5 years?

The CRO market in APAC, the fastest growing region in the world, has been increasing at an FY2013– 2015 CAGR of 19.5% (China, 33%; Japan, 10%) and the trend is expected to continue for the next 5 years. The two most significant market growth drivers specific to Asia are the reduction of drug lag and cost. The global growth drivers of vendor consolidation and increased outsourcing penetration are significantly more pronounced in Asia where the top 5 players have a staggering 67% share of the market (compared to 38% globally).

Which countries in Asia are exhibiting promising growth in the CRO space and why?

From a customer segmentation perspective, the fastest growth in the region comes from Chinese pharmaceutical companies conducting China-only trials or needing to outsource global trials due to the lack of in-house expertise,with a growth rate of up to 90%. However, it must be noted that the base is quite small as the total R&D spend of all Chinese pharmaceutical companies combined is still lower than that of just one or two large western biopharmaceutical companies. Chinese companies have little need for pan-Asian trials at the moment as the cost of performing China-only trials for domestic filing is still tenable. China-only trials tend to be outsourced to Chinese CROs while global trials are outsourced to global CROs. However, there is an increasing trend to engage global CROs for China-only trials that are expected to go global. The second fastest growing segment is Japanese pharmaceutical companies needing to outsource panAsian trials due to a lack of

expertise and needing to include other East Asian populations for domestic filings. The cost of conducting clinical trials in Asia is significantly lower than that in Japan by as much as 10 fold. In addition, there is a much higher research population in Asia outside Japan that qualifies for domestic registration in Japan. The outsourcing penetration in Japan is just 20% compared to ~50% in the US so there is significant room for growth. The value of the Japanese CRO market is $1.38 billion, with much of it from Japanese pharmaceutical companies, so the base is much more significant than that for China pharmaceutical clinical outsourcing,although the growth rate is just 10%. The most significant customer segment for growth for global CROs remains global trials because of the large revenue base. The driver for growth in this segment is a steady reduction in the drug lag in both Japan and China. The incentive to include Japan in global clinical development is significant, as only 10% of drugs in the world's second largest market for pharmaceuticals is generic (compared to 50% in the US/EU) and the main barrier previously has been the drug lag.