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Proprietary Intelligence

China FDA's plans to speed up trial and regulatory timelines could revive waning sponsor, CRO interest – experts

Five year CTA delays previously put-off CROs and sponsors

CROs may look to partner or acquire in China again

Local, small CROs competitive with better hospital access

Upcoming changes to Chinese medicinal regulations could lead to a renaissance in country participation in multiregional clinical trials (MRCT), experts said. The government's move to rectify long-standing clinical trial approval (CTA) and regulatory time lags could also lead to more global CROs entering the market, they added.

Strategic partnering with local CROs active in multinational trials could be one avenue for larger CROs, experts said, although there was debate on whether acquisitions of local players would be ideal.

The Chinese FDA's (CFDA's) new commissioner plans to offer scientific advice to sponsors prior to Investigational New Drug (IND) submissions as well as work with international agencies to gain experience on regulating new drugs, said Tao Wang, CFDA's clinical office director during a presentation at a DIA meeting earlier this year. The agency also intends to boost staff levels from its current 120 heads to 1,200 by 2020, said Wang and Haixue Wang chief pharmacist, CFDA's Center for Drug Evaluation (CDE) at the same meeting.

The key goal is to shorten review timelines and encourage international sponsors to do MRCTs in China, both CFDA regulators added. All experts were confident the CFDA will make the necessary changes.

As China is now the second biggest pharmaceutical market in the world, companies are keen to include Chinese sites in Phase II and pivotal trials to achieve regulatory approval, experts noted. Increasing biomedical investment from the government and private sector also adds to China's appeal, said Amar Kureishi, head of Asian drug development for Quintiles (NYSE:Q).

The news is encouraging as growing lags in trial approval timelines - in recent years as high as five years -- meant foreign companies were increasingly avoiding including China in multinational trials and CRO interest had waned, some experts noted. For example, Kureishi referred to BioPharm Clinical data showing 54 MRCTs including China began in 2014 compared to 90 in 2013.

The lag in CTA and New Drug Approval (NDA) approval timelines for international products (those not manufactured in China) is at its worse since a change in review practice associated with MRCT acceptance in 2014, said Neil McAuslane, scientific director, Centre for Innovation in Regulatory Science (CIRS), London, UK. Among other issues, the changes meant that even if the CTA was waived due to acceptable existing data, the applicant would have to return to the back of the queue for an NDA application to gain an import drug license, he explained.

This system added further strain to the CFDA's already low personnel resources, experts added.

CRO activity

Regulatory setbacks have caused sponsors and international CROs to be hesitant about investing further in China, Lei Li, a partner at Sidley Austin in Beijing, China, noted. However, if the CTA process is expedited, more MRCTs could include Chinese sites by sponsors, said Li. Small sponsors in particular abstain from China in MRCTs, having less resources than big pharma to wait-out delays, he noted. These small sponsors would turn to CROs that have experience in international trials including China, he said.

For CROs looking to enter the market, building a business without local support would be unadvisable so partnering with local CROs would be the key, said Kureishi. As the Chinese regulations evolve, it is crucial to have a local presence aware of the regulations, Kimty Bui-Van, head of regulatory affairs and pharmaceutical services, ProductLife Group, France and a source from a Japanese CRO with capabilities in China agreed.

Quintiles started with strategic partners in the region and in 2011 launched its own Chinese CRO subsidiary, Kun Tuo, Kureishi said. Other CROs are trying to set up such offerings, he noted.

Acquiring local CROs focussed on multinational trials could be another option for market entry, Mark Shapiro, vice president of clinical development at Clinipace said, noting it and other international CROs have generally done this.

The majority of Chinese CROs work on local trials, said Li, noting the bigger players like WuXi PharmaTech (NYSE:WX) have some international trials. Local CROs like Tigermed also run some international trials, said Kureishi.

However, Kureishi argued acquisitions can be difficult in China due to a lack of transparency by Chinese firms. Likewise, Shapiro said acquiring small China-focussed CROs would be more difficult than ones already working on MRCTs since they may not be familiar with international clinical trial regulations. High turnover of staff within Chinese CROs can also make handover during acquisition tricky, Kureishi added, warning there is no quick route to Chinese market entry.

Yet, Li noted as local CROs will have good access to Chinese hospitals that global CROs may not have, the acquisition of local players as subsidiaries may make good business sense.

by Natalie Morrison in London

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