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Proprietary Intelligence

South Korea's surge in foreign-sponsored trials drives further opportunities for global pharma and CROs – experts

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Big pharma interest in earlier Korea-based trials

South Korea's foreign sponsor and CRO attraction over the last decade has scope to increase if it can improve capabilities in early-phase and complex trials, experts said.

The region may also continue to attract multinationals aiming to exploit a potentially more streamlined drug approval process across Asia, they added.

Clinical trial registration in South Korea shot up from 17 multinational-sponsored trials in 2002 to 296 in 2015, according to figures from Korea's Ministry of Food and Drug Safety (MFDS). The US National Institutes of Health clinical trials database indicates 293 trials registered in Korea so far in 2016, and ranks South Korea first in Asia by number of protocols.

Korea National Enterprise for Clinical Trials (KoNECT), an organisation funded by the government since 2007 to improve the quality of research sites - drove the increase in trials, agreed Greg Koski, CEO of US-based Alliance for Clinical Research Excellence and Safety (ACRES) and Fred Pritchard, VP, global drug development, at US CRO Celerion. Koski and Pritchard said KoNECT's funding of an accreditation programme for sites and training for clinical monitors over the last decade improved start-up times, completion rates, accuracy of data, and enrolment. According to KoNECT, while the number of global clinical trial sites decreased 14% over 2010-2014, South Korea grew 6.8%, ranking it 11th in 2014 globally for industry-sponsored clinical sites. But the site standards are not very robust, said Koski, adding ACRES and KoNECT are working together to improve site efficiency by creating global site accreditation.

Site standards and Phase I regulation has room for improvement

Koski and Pritchard added although Korea has strongly attracted late-phase research, it lags in capabilities for early-phase trials - still limited by red tape - and complex studies, such as those for precision medicine. Pritchard said CROs Parexel (NASDAQ:PRXL), Covance, owned by LabCorp (NYSE:LH), INC Research (NASDAQ:INCR), Quintiles (NYSE:Q) and PPD have placed later-stage clinical trials in South Korea, but now they and large pharma, among them J&J (NYSE:JNJ), Merck (NYSE:MRK) and Sanofi (EPA:SAN), are interested in moving earlier-phase trials into the country.

KoNECT President Deborah Chee said KoNECT and umbrella initiative Korea Clinical Trials Global Initiative (KCGI) have been working to improve early-phase and complex clinical trial capabilities by establishing clinical pharmacology units - supporting Phase I research -- at 15 university hospitals by 2014. A separate investment was made in early phase-focused personnel, equipment and training at five trial site clusters across the country, and in translational research, said Chee and Min Soo Park, KCGI Chair.

Additional hurdles to overcome in order for Korea to retain foreign sponsor engagement include the need for greater global visibility and a more transparent review process from MFDS, said Park. Chee added KoNECT may work to allow a single institutional review board (IRB) review for multi-site trials, instead of currently required separate submissions. Pritchard noted medium-sized CROs like Celerion moving into South Korea should be aware of different business requirements from the US - like needing to establish a physical office in Korea before obtaining a formal business licence and hiring staff.

Chee added KoNECT is also consulting with the industry to reduce trial review bottlenecks, launching a campaign to improve patient awareness of trials, and developing KoNECT Integrated Clinical Trial Information System (KIIS), a database available to sponsors with epidemiology and investigator data. KoNECT last year opened a support centre for foreign sponsors, with a match-making service with local partners, said Chee.

Gateway to earlier Asia approvals and launches

For multinationals wishing to secure earlier market approvals in Asia and decrease the launch lag after EMA and FDA approvals, conducting research in South Korea is the best gateway, said Pritchard.

The common lag is partly due to Korean, Japanese and Chinese regulators' requirement that

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some research, often pharmacokinetic, be performed in the countries' own ethnic populations, said experts. Typically pharma companies leave Asian regulatory strategy until Phase II or III when they realise they have neglected to include enough Asian subjects, said Kenneth Kim, CEO of US CRO WCCT. "These companies are leaving money on the table by neglecting a market for five years, and it can amount to USD 100m or more per year in lost sales," said Kim, whose company, like Celerion, Parexel and a handful of other CROs, performs bridging trials in the US with patients of Japanese ethnic origin in order to show safety and efficacy in Asian populations.

There has been a gradual and significant decrease in the global need for bridging studies, Park confirmed, which he attributed to multinationals moving more trials to South Korea, and so including Asian subjects throughout the clinical programme. Kim noted starting clinical programmes in Asian patients from the beginning is cheaper than performing a bridging study, which costs around USD 1m.

As pharma moves away from viewing Asian markets as an afterthought, many will decide Korea is the easiest Asian country for US and European companies to run trials, said Pritchard, especially as regulators in Japan, China and South Korea agreed to begin accepting Asian PK data from each others' populations. Since 2006, the Japanese regulator, PMDA, has approved more than 20 compounds supported by Asian sub-group analysis data obtained abroad, including in Korea, Chee confirmed.

Chee agreed Korea will prove the most attractive region for sponsors seeking Asian trials, citing the shortest study start-up time of all Asian countries. Trial review for study initiation takes 30 days in South Korea if there are no supplementary requirements, she said, and on average takes four to eight weeks, with the IRB process running in parallel. Pritchard claimed the Japanese regulator is perceived to lag in trial approval time. The Chinese regulator, CFDA, can take up to 18 months for study approval, as amendments to trial applications require restarting the review process, according to research by PPD.

by Fiona Barry in London

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