

CLINICAL TRIALS *Advisor*[®]

Indian Clinical Trials Industry Booming, Experts Say

The clinical trials industry in India has taken off over the past few years as trials have become standardized, predictable and quickly approvable, experts say.

A survey of publicly available data on the NIH's ClinicalTrials.gov registry shows the number of trials under way in India has risen from 50 in 2002 to 560 today, a total that does not include non-U.S. IND studies or investigator-initiated research, Dan McDonald, vice president of business development of Excel Life Sciences, said at an RxTrials Institute audioconference.

"Until 2005, India was best known as a generic powerhouse. It had poor intellectual property laws and long start-up times, so it was not considered a clinical trials destination," McDonald said.

The FDA has conducted eight site inspections in India since 2005, half of which resulted in a finding of "voluntary action indicated" while the other half were deemed "no action indicated." Another six FDA inspections are planned this year, Excel's President Vijay Kumar said.

Trial approvals from regulators are accomplished quickly because they comply with FDA standards or those of the HHS Office for Human Research Protections (OHRP). Global clinical trials typically receive approval for Indian sites from the country's Drugs Controller General in four to six weeks, Kumar said. Sponsors can obtain provisional IRB approval to get a trial moving before the Ministry of Health gives the green light.

Mumbai has 14 OHRP-registered IRBs, New Delhi has 13, Bangalore and Chennai have 11 each, Hyderabad has eight and Pune has four, Kumar said.

The number of clinical investigators available is fairly evenly distributed among these and other major Indian cities, McDonald added.

Perhaps the strongest advantage of the Indian clinical research enterprise is its human capital. It has a well-credentialed base of physicians, many of whom are computer literate and fluent in English. "Soon there will be 1,000 qualified investigators in India," McDonald said. There also are large patient populations that have not received any healthcare for a range of diseases.

"Indian investigators are very excited about doing international clinical trials and publishing journal articles in India and internationally. There is an enthusiasm you might not see in some of the more mature markets," McDonald said.

Matchmaking Sponsors and Sites

Once an international sponsor has decided to conduct a clinical trial in India, the question arises of how to find appropriate sites. "The least common way is sponsors identifying and signing up sites. At the same time, Indian sites haven't built up the confidence to solicit sponsors," McDonald said.

This creates a need for intermediaries. There are two main ways of structuring the relationship between sponsors, sites and intermediaries, McDonald said. In the first model, the sponsor deals directly with a trial management organization (TMO) or site management organization (SMO), which selects sites and enrolls patients but hires a contract research organization (CRO) to do the monitoring to avoid a conflict of interest. In the other model, the sponsor deals directly with a multinational CRO, which manages the project and contracts with a TMO or SMO to select and manage sites and monitor study content.

TMOs and SMOs “have a slightly negative connotation in the U.S.,” McDonald said. “The concept peaked in the 1990s and early 2000s and has gone into decline among sponsors and sites. But in India, there is a need for them among inexperienced sites.”

Clinical investigators in India have huge patient loads and lack the time to handle day-to-day study conduct activities, and site personnel require ongoing training and support, including good clinical practice (GCP), standard operating procedures and IRB setup and guidelines.

TMOs and SMOs offer on-site placement of clinical research coordinators (CRCs), ensure high quality data reporting and help with patient screening, enrollment and retention. A recent survey of more than 900 Indian sites found that fewer than 15 percent had a full-time CRC, McDonald said.

Sponsors also must take into account the need for training on such subjects as GCP, ethics and consent, patient recruitment and retention, investigator relations and communication, and other “soft” skills.

It is crucial to be alert to cultural variations within India. For example, different areas of the country have different vacation times. “One site may have peak enrollment between October and December, and another site may be closed then,” Kumar said. “Religious events and social practices can change the course of the study.” — Martin Gidron

