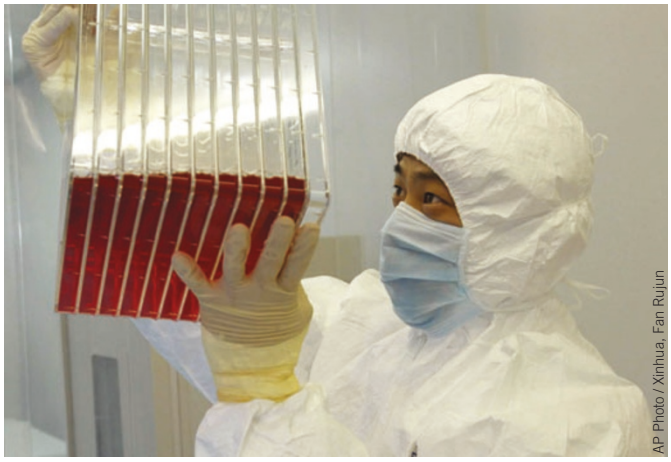
China beckons to clinical trial sponsors

The clinical trials market is opening up in China. The most recent evidence has been provided by the Danish Centre for Clinical and Basic Research (CCBR), which announced its intention to establish clinical research facilities in Beijing, independent of the state authorities. Low cost and ease of access to patients are the main incentives for clinical trial outsourcing. But several hurdles face biotech companies looking to locate their trials in China, including poor data standardization, delays in gaining trial authorization from regulators and questionable ethical standards.



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A Chinese scientist observing an experimental SARS vaccine currently in the clinic. Increasingly, the country is attracting foreign biotech companies seeking to outsource their clinical trials.

On May 23, CCBR announced its intention to establish a clinical research center and an international clinical testing laboratory in Beijing. With a $10 million budget, CCBR is the first clinical laboratory that is independent from the hospitals in China, according to John Christiansen, chief executive of CCBR. To a certain extent, this heralds the liberalization of the clinical trials market there; others centers may follow.

Until now, the only institutions authorized to perform clinical trials in China have been major state-run hospitals. Min Liang, vice general manager of Shanghai-based gene therapy company Sunway Biotech, welcomes the diversification of trial options. With more independent clinical trial providers, biotech companies could avoid the limitation of certain hospitals in designing clinical trials and the poor coordination between different hospitals.

So why has the Danish center chosen China rather than India or another Asian developing country? Because of the cost-effectiveness of doing trials in China. Ying Zhang, marketing director at Beijing-based clinical trial contract research organization (CRO) Excel Medical Technology, estimates that the cost of a clinical trial for a new drug in China is only half of the amount in the United States or Western Europe owing to lower labor and infrastructure costs.

What's more, Xiangming Wang, general manager of CCBR China, explains that CCBR opted for China over other countries in the region because they could find better medical and transportation infrastructures, with easier access to patients. These advantages have already attracted many international pharmaceutical companies which have Chinese clinical trials underway.

Despite such advantages, some hurdles remain. The new trials approval process of China's State Food and Drug Administration (SFDA) can take up to one year. Zhi'ang Wu, director assistant of Drug License Authorization Center of SFDA, admits the process of evaluation and approval is quite slow owing to the sheer volume of applications (only two thirds of the estimated 1,250 applications for authorization of new trials and new drug applications received each month are processed). Delays in gaining Chinese trial approvals could affect the timing of international multicenter projects, says an insider at Beijing-based CRO Quintiles Asia, a subsidiary of Quintiles Transnational of Research Triangle Park, North Carolina.

There are signs, however, that SFDA is accelerating the approval process for trials of innovative medicines to encourage research and development of such drugs, according to William Keller, general manager of Shanghai-based Keller Pharma Consultancy and former head of Roche in China. In addition, China's SFDA has also increased its efforts to promote good clinical practice (GCP) by releasing strict and standard rules in 2003 and 2004 and introducing compulsory GCP training in April 2004.

The implementation of the GCP rules will not necessarily make up for Chinese trials' poor level of compliance with Western standards though. For example, data standardization may not be adequate and issues with consent have been reported (*Nature* **435**, 138, 2005). That's because, in the past, Chinese doctors often carried out clinical trials on generic medicines whose efficacy and safety had already been proven abroad, according to Excel Medical Technology's Zhang. Intense competition among generics companies has resulted in lower standards—including a lack of sufficient training, proper management and reasonable clinical trial plans—in the race to bring products to market.

To remedy this situation, Quintiles has had to train Chinese doctors in adopting Western standards, says the Quintiles Asia insider. In addition, Quintiles Asia has amended its existing agreement with Beijing-based Peking Union Medical College Hospital (PUMCH) to ensure its services operate under the same standardized processes, controls and reporting mechanisms as other Quintiles facilities.

CCBR has devised another solution to guarantee highest standards. It will establish its own clinical trial facilities within state-owned Chinese hospitals licensed to perform clinical trials. CCBR will hire high-quality doctors from a wide variety of hospitals instead of relying one or two hospitals. "This method can make us free of the problems of Chinese hospitals like low efficiency and relaxed disciplines," says Wang.

Despite the harmonization of standards at some clinical trials facilities, it remains to be seen whether the US Food and Drug Administration or European Medicines Agency will accept data obtained from clinical trials carried out in China. Already foreign organizations like Quintiles, CCBR and Canadian company MDS of Toronto, have been seeking endorsement of agencies like the American College of Pathologists to gain recognition for their work there. "If data collected from our different centers are similar, the credibility and acceptability of clinical trials in China will need to greatly improve," Wang says.

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