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ASIA EDITION

Corruption hampers China's growth

September 5, 2013 | Analysis | By BioSpectrum Bureau



The growth story of the clinical research industry in China speaks of perfection, good timing and untapped potential. All the basic characteristics that are native to China further add to its enormous clinical research market potential. China's pharmaceutical industry and its clinical research market witnessed spurts of growth at the right time. Furthermore, China's untapped potential in terms of its large genetic pool of recruitable subjects along with lower costs of operation, doubled its recognition globally and this led to substantial increases in revenues in no time. However, all that is now being overshadowed since the country's pharmaceutical segment came under a cloud of corruption this year.

From shocking revelations about drug safety lapses to worrisome reports of misconduct during clinical trials have shrouded the industry over the last few years. Initially investigation reports emerged of three academicians being sacked from Zheijang University in China over plagiarism and fake research. Then reports of fraud and poorly managed trials by Bristol-Myers Squibb (BMS) and contract research organization PPD emerged. British drugmaker GlaxoSmithKline (GSK) was next in row. The company's Chinese operations came under strict scrutiny after it dismissed the head of its China research and development (R&D) center following manipulation of clinical data in a published paper.

This brought skeletons tumbling out of GSK's corruption and bribery ridden closet. China's struggles to regulate its booming clinical research industry were revealed early in 2013, when a Beijing court was forced to question how trial-runners pay compensation to patients. Raking up the issue was a legal suit involving an 84-year-old woman who developed serious side effects after participating in a anti-thrombosis drug clinical trial sponsored by Bayer Pharmaceuticals. She had to withdraw from the study and get further treatment as a result of the side effects. Bayer, which covered $530 as part of the host hospital's mandatory insurance coverage, had to pay $64,000 to the lady, as she claimed that her actual medical costs came upto $194,000.

Amidst these scandals, the US Food and Drug Administration (FDA) rapped the Chinese clinical trials industry. The regulator questioned the country over sloppy data generation and irregularities in clinical trial procedures. The US drug regulator also questioned whether large trials in countries like China, which were ridden with data shortfalls, were a viable basis for approving treatments. The hazy regulatory environment in China and the on-going trail of pharmaceutical corruption scandals in the life science industry are two of the major hurdles in China's path towards successful and fruitful functioning.

China's stringent regulations require that clinical trials have to be conducted with Chinese patients, before a new drug can be marketed in the country. Furthermore, to receive approval for drug imports, marketing authorization from a reference country other than China must be available. Moreover, the fact that companies need to complete phase II compound testing elsewhere before they can begin study in China, causes severe delays. These hurdles have prevented the country from participating in simultaneous global drug development. Added to this, hospitals in the country need to be certified by the CFDA before they can participate in clinical trials. Reports claim that the average approval time of clinical trials is 145 days, while in the US and Japan approvals are sanctioned in 30 days. The language barrier still looms large, hindering progress of the industry. Long drawn ethical approvals then follow, increasing the time frame by another nine-to-ten months.

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Clinical trial duration, a challenge

In the last few years, the duration of performing clinical trials has also emerged as a major challenge for China's clinical research industry. As per Chinese government reports, the country averages an efficient 5.5 months to first patient first visit (FPFV). As compared to this, the United Kingdom and Scandinavian countries have held the record of being the most efficient, averaging around three months in duration, India averages over 12 months and the US averages seven months. However, factors such as disease burden act as motivation for the functioning of clinical research firms. The disease burden in China is growing at an alarming pace. It is estimated that two years back there were 92 million people with diabetes and 148 million with pre-diabetes in China.

Between 2011-16, the Chinese government planned to invest $1.5 billion in new drug development. A study conducted by Bayer Schering Pharma revealed that China outpaced the rest of the world in respect to many performance indicators. The study showed that China can provide double the worldwide average of available patients per site.

Further, venograms, which is a radiograph of a vein after injection of a radiopaque substance, are available at 95 percent of Chinese facilities, as opposed to 92 percent globally. In terms of the availability of clinical research associates, China ranks fourth in the world. Today, pharmaceutical majors from across the world are not just outsourcing their work to Chinese CRO's but are also entering into long-term partnerships with them. These partnerships mean sharing profits and co-developing drugs specifically for the Chinese market. A whole host of US- ased CROs are further setting a trend by making strategic partnerships with Chinese companies to study the Chinese regulatory system more closely.

In recent times, China's Center for Drug Evaluation released a long-term proposal document that charts out the country's action plan to improve the regulation and management of clinical trial data. The proposal to standardize pharmaceutical clinical trial data management' laid down some ambitious medium to long term goals for improving the management of clinical trial data in the country. It also acknowledges the lack of unified rules and variable standards. The three core points mentioned in the proposal are preparation of unified rules on data management, setting up an accessible registry of trials and building a database.

Experts claim that addressing these issues, which have in the last decade of boom proved to be China's clinical trial bottleneck leading to a stunted drug efficacy and international competitiveness, would help the country achieve dominance in the sector globally.