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NEWS

80% of China's clinical trial data are fraudulent, investigation finds

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Just over 80% of clinical trial data submitted to support new drug registrations in China have been revealed as fraudulent or substandard by the country's drug regulator.

An investigation of data for 1622 new drugs submitted to China's State Food and Drug Administration (CFDA) for registration said that 1308 of the applications should be withdrawn because they contained fabricated, flawed, or inadequate data from clinical trials.[1]

In a damning report released on 9 September the CFDA described the findings of widespread fraud as shocking and vowed to crack down on what it described as a "chaotic" situation in the country's clinical trials industry.

Much of the blame was attributed to the country's loosely regulated clinical research organisations, which industry insiders claimed operate in cut throat competition and resort to data fraud to gain drug registrations.

The CFDA report also concluded that there had been "breach of duty by supervision departments and malpractice by pharmaceutical companies, intermediary agents, and medical staff" in clinical trial fraud.

In a one year investigation as part of a tightening up of drug registration standards, the CFDA assigned 366 staff to verify the details of clinical trial dossiers supplied to support drug registrations.

The investigators found a variety of problems, such as discrepancies between original trial data record books and submitted files and, in some cases, a complete lack of raw data. The investigators also found that, in many cases, data had been fabricated or altered and that for some trial reports there was clear evidence that data had been reported selectively or adverse events data manipulated or hidden. In one example data were declared suspect by investigators because they had apparently been recorded by staff who had not yet started employment.

The report listed 10 institutions with the highest volume of clinical trial submissions, which included Sichuan University Huaxi Hospital and Peking University Number One Hospital. The report also listed the top 10 clinical research organisations that submitted clinical trial data, which included Guangzhou Boji New Drug Clinical Research Center and the Shenyang Yiling Pharmaceutical Technology Co.

The CFDA said in its report that it aimed to further intensify the scrutiny of new drug applications and to adopt a "zero tolerance" approach to clinical trial data fraud. "One year on, after undergoing verification, the finding of clinical trial chaos and fraudulent behaviour is startling," it noted. "We will deal severely with any instances of fraudulent and deceptive behaviour in relation to drug applications and unceasingly pursue the responsible officials."

Reporting on the findings, China's *Economic Information Daily* quoted an un-named hospital manager as saying that the report came as no surprise to many in the healthcare sector because clinical trial fraud was "an open secret."[2]

The manager said that much of the fraud could be attributed to competition between China's numerous generic drug manufacturers, who were eager to have "me too" drugs registered to take a share of the country's booming $108bn (£84bn; €97bn) drug market.

Zhang Mingyu, vice president of the China Pharmaceutical Industry Association, told *Health Times* that many drug companies outsourced clinical trials to contract research organisations that offer a "no win, no fee" service for drug registration applications.[3]

The CFDA report is the latest development in the Xi Jinping government's crackdown on corruption and fraud in China's healthcare and medical research sector. In May 2015 the government detained Wang Yu, a former head of the health ministry unit responsible for clinical trials, as part of an investigation into bribery.[4]

At the same time the National Health and Family Planning Commission enacted a new policy that required clinical trials to be run under the auspices of hospital research committees rather than individual doctors or their departments.[5]

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