## 80% of Data in Chinese Clinical Trials Have Been Fabricated

## Oh crap.

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A Chinese government investigation has revealed that more than 80 percent of the data used in clinical trials of new pharmaceutical drugs have been "fabricated".

The report uncovered fraudulent behaviour at almost every level, and showed that some pharmaceutical companies had hidden or deleted records of potentially adverse side effects, and tampered with data that didn't meet their desired outcomes.

In light of the findings, 80 percent of current drug applications, which were awaiting approval for mass production, have now been cancelled.

The investigation, led by the Chinese State Food and Drug Administration (SFDA), looked at data from 1,622 clinical trials for new pharmaceutical drugs currently awaiting approval. The applications in question were all for Western medicine, not traditional Chinese medicine.

The SFDA found that the more than 80 percent of the data failed to meet analysis requirements, were incomplete, or totally non-existent.

Not only did the report find that many of the 'new' drugs awaiting approval were actually a combination of existing drugs, they also showed that many clinical trial outcomes were written *before* the trials had actually taken place, and the data had been simply manipulated to match what companies wanted to find.

Worst of all, it wasn't just a few scientists or pharma companies doing the dirty work. The report found that pretty much everyone involved was guilty of some kind of malpractice of fraud.

Perhaps most worryingly, even third party independent investigators tasked with inspecting clinical trial facilities are mentioned in the report as being "accomplices in data fabrication due to cut-throat competition and economic motivation".

In other words, China's pharmaceutical industry has a really, really big problem - and the SFDA now has to worry about all the other new drugs approved as "safe" based on potentially unreliable clinical trials.

The problem isn't regulation - Chinese clinical trials have similar guidelines in place as the Western world, with three phases required to test for safety, efficiency, and whether or not the new drug is better than the existing treatment.

Those guidelines are all well-communicated and inspected by third parties, but there's clearly a "lack of adherence to them", explains Ben Hargreaves from PharmaFile.

The SFDA report was released by the state-owned *Economic Information Daily Newspaper*, and, as yet, there's no English version available online to go over with a fine-toothed comb, so for now, we're taking the Chinese media's word for it.

But as shocking as it all sounds, *Economic Information Daily Newspaper* also cites unnamed industry insiders who weren't surprised in the slightest at the revelations.

"Clinical data fabrication was an open secret even before the inspection," the paper quoted an unnamed hospital chief as saying, reports Radio Free Asia.

According to Luo Liang, a Chinese healthcare professional, the problem stems from the fact that local pharmaceutical companies trying to produce Western drugs struggle to turn a profit.

"The domestic market for Western pharmaceuticals in China is either confined to very straightforward generic products that have been around for a long time ... or revolves around joint-venture pharmaceutical manufacture with foreign companies," Liang told Sing Man for Radio Free Asia.

"Either that, or Chinese pharmaceutical factories get hold of the formula for certain drugs whose patents have expired," he added. "There are no new drugs in development in the same way that there are overseas ... I don't think that the 80 percent figure is overstated."

While traditional Chinese medicine wasn't covered by this investigation, some think even worse practices are going on in that industry, but are less likely to be uncovered because they're "harder to regulate".

"It's not just the medicines," he said. "In China, everything is fake, and if there's a profit in pharmaceuticals, then someone's going to fake them too."

As damning as this problem is for China's scientists, they aren't the only ones that are under more and more pressure to publish positive and "groundbreaking" results in order to keep their jobs.

A study published earlier this month revealed that the enormous pressure on academics is acting like a form of natural selection, and evolving science into something "shoddy and unreliable".

Let's just hope reports like this serve as a wake-up call to show what's really at stake when we can't trust researchers anymore - because that's a pretty scary reality to consider.