Drug Trials

London, 8 o’clock. Six men have just taken a new drug. Injected directly into their bloodstreams, it’s not meant to have any side effects. Within minutes, however, the first man is experiencing headaches and chills; moments later, the others follow suit.

By 9 o’clock, one man has passed out and all six are in serious danger. Their temperatures are rocketing, their pulses are racing and their blood pressure is falling. Without immediate medical attention, these men will die.

Yet this is not the story of a recreational drug gone wrong. These six men were taking part in a clinical trial to test the efficacy of a potential anti-leukaemia drug, TGN1412. It was only thanks to tremendous effort from doctors that the men escaped, eventually, with their lives.

In the months that followed, researchers tried to establish what went wrong. No one expected the adverse reaction as there had been no ill effects in animal trials. But soon new information came to light: an analogous compound had been trialled in humans ten years earlier, with similar results – and the data had never been published. Evidently, the result was not what the researchers had been looking for.

This incident, and others like it, have led Ben Goldacre and the charity Sense About Science to start the AllTrials campaign to demand that all clinical trial data be released.

“It turns out about half of all clinical trials are never published,” said Chris Peters, campaigns officer at Sense About Science. “It’s an absolute disgrace to think that we would not now be able to calculate how many trials have been conducted.”

Currently, pharmaceutical companies are not obliged to publicise their clinical trial results: they can highlight only the trials that flatter their products. Not only does this put unnecessary risk on later subjects of clinical trials, but it exposes the initial participants to danger for no benefit.

“It’s really quite unethical, especially as inherently clinical trials have an element of risk for the participant,” said Peters.

In fact, missing data harms more than just trial participants. In the UK, the National Institute for Health and Care Excellence (NICE) advises the NHS on which medicines are worth buying. Yet it does not have full access to clinical trial data, meaning that the NHS may be spending money on drugs that are no more effective than what is currently on offer.

“In order to make a decision about whether a drug is effective or not, we need to have access to as much of the information about its effectiveness as possible,” said Simon Wilde, associate director for communications at NICE. “If data’s not been published, it makes it very difficult to make decisions.”

Tamiflu, the anti-flu drug, is one such example. According to its manufacturer, Roche, it provides a “67 percent reduction in secondary complications [of flu] such as bronchitis, pneumonia and sinusitis.” Consequently, governments across the world stockpiled the drug in the wake of the bird flu pandemic, with the UK Government alone spending £424 million.
Yet this claim was based on data that only Roche had full access to – of the ten trials performed, just two were published in a journal. It took nine years for researchers at the Cochrane Collaboration to obtain more data, and with this they concluded that Tamiflu made very little difference to the complications of flu. Unfortunately, their report came too late for the countries that collectively spent £4.7 billion buying the drug.

For patients and public alike, then, this campaign is sorely needed. By withholding clinical data, not only are drugs companies misleading patients and doctors, but they are belittling the vital role that trial participants play in the pharmaceutical industry. Without clinical trials, none of the medicines that NICE reviews would even exist.

“Companies have a duty to the people who take part in these trials,” said John Davidson, whose six-year-old son, Henry, is part of a clinical trial. “They have given of themselves to advance medical research.”

Henry is being treated for acute lymphoblastic leukaemia, and for the trial he must undergo an as-yet untried treatment. Trials like these mean that the disease has one of the highest survival rates of all cancers, but as a parent, John wants what is best for his child.

“I wouldn’t have had him take part in a trial if I thought it was simply for commercial gain for an organisation,” he said. “The idea that [the data] wouldn’t be published at the end is dreadful to me.”

If the AllTrials campaign succeeds, people like John and Henry – and the men who trialled TGN1412 – will get the respect they deserve. If not, John believes pharmaceutical companies may find themselves facing a rising tide of public anger:

“Drugs companies have more than their shareholders to answer to - they have people to answer to, they have patients to answer to, and I think it’s absolutely essential that that information is made public.”