



#### Description

Scientific misconduct is a concern for both the research community and the general public. This is especially true for clinical trials, as the results of these studies can directly affect patient health. Clinical trials also impact access to medicines and other treatments.

A recent report, however, found that some US universities <u>do not publish clinical trial results</u> on time. While the law expects all US colleges to post clinical trial results on a public register, within one year of the end of the study.

## Missing results

The report was published by TranspariMED and Universities Allied for Essential Medicines (UAEM), also covered by *Nature*. Both groups campaign for transparency in research.

The researchers studied the US colleges that run the most clinical trials. Of the 40 schools, 25 did not publish the results on time. There was also a big difference between colleges. Only 15 colleges fully complied with the law. Just five colleges sponsored half of the missing studies. The University of California San Francisco failed to publish results of 17 trials. Columbia University reported just 17% of trials on time.

Overall, the researchers looked at 450 trials run by the 40 colleges. They found that results of 140 studies (31%) were missing from the register.

On the other hand, the universities put forward their statements in their support. The University of California San Francisco stated that 10 of their missing trials were overdue, while other missing results were due to delays in data analysis or changing completion dates. Similarly, Columbia University insisted out of the 15 late studies, only eight were complete.

# **Reporting Results: The Law**

A 2007 federal law required results of most trials to be published within a year. This law came fully into force in January 2017. Results must be published on the government website <u>ClinicalTrials.gov</u>. Once posted, results are freely available to the public. Only a few studies, such as Phase I safety trials, are



exempt from the rule.

Universities that do not post results are in breach of the FDA Amendments Act and could face fines of up to USD10,000. They are also neglecting World Health Organization (WHO) guidelines. These state that results must be posted on a public register within one year.

## Impact on the Research Community

For the research community, posting clinical trial results on time has many benefits. The one-year deadline means faster sharing of research results. Researchers do not need to wait for journal articles. This increases the pace of medical progress. The short deadline also reduces the risk of research "waste." This might happen when a researcher moves on to another job, for example.

Public registers can reduce scientific misconduct, by comparing results with the stated aims of a trial. This should <u>help to avoid trial outcomes</u> being "switched" or suppressed.

The US is not alone in this problem. A 2018 study looked at trials sponsored by EU universities. The authors found that 89% were not reported within a year. EU law requires results to be posted on the EU Clinical Trials Register.

## **Tackling the Problem**

A study conducted in 2015 on trials sponsored by US colleges between 2008 and 2015 revealed that 90% did not publish their results within one year. After a public backlash, many schools tried to reduce the backlog. A 2017 follow-up study found that the situation had improved. In total, colleges had posted results of over 500 older studies. However, results of 777 trials were still missing.

In a positive sign, many colleges made a big effort to post missing results. Five colleges posted more than 85% of their missing trials. By implementing stricter laws on the universities with respect to the registration of clinical trials and making them abide by these would possibly help combat this issue effectively.

How do you think the research community be affected by this partial disclosure of the clinical trial results? Please share your thoughts in the comments section below.

#### Category

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