# BMJ editors call for COVID-19 vaccine and treatment data to be available for public scrutiny

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Data on COVID-19 vaccines and treatments should be fully and immediately available for public scrutiny, argue editors at *The BMJ* today.

Twelve years ago, The BMJ called for the release of raw trial data for the antiviral drug Tamiflu after it came to light that governments around the world had spent billions stockpiling antivirals that had not been shown to reduce the risk of influenza complications, hospital admission or death.

Now, The BMJ's editor in chief Kamran Abbasi, along with senior editor Peter Doshi and former editor in chief Fiona Godlee, warn that these errors are being repeated.

"Today, despite the global rollout of COVID-19 vaccines, the participant level data underlying the trials for these new products remain inaccessible to doctors, researchers, and the public—and are likely to remain that way for years to come," they write. "This is morally indefensible for all trials, especially those involving major public health interventions."

They point out that Pfizer's pivotal COVID vaccine trial was funded by the company and designed, run, analysed and authored by Pfizer employees. The company and the contract research organisations that carried out the trial hold all the data, but Pfizer has indicated that it will not begin entertaining requests for trial data until May 2025.

Moderna says data "may be available … with publication of the final study results in 2022" and as of 31 December 2021, AstraZeneca may be ready to entertain requests for data from several of its large phase III trials. But as its website explains, "timelines vary per request and can take up to a year upon full submission of the request."

"We are left with publications but no access to the underlying data upon reasonable request," write the editors. "This is worrying for trial participants, researchers, clinicians, journal editors and the public."

Companies do provide far more granular data to regulatory agencies as part of the regulatory review process, they explain. As such, study reports are now available and missing appendices may be accessible through freedom of information requests.

However, they point out that most regulators do not hold participant level datasets, and industry, which holds the raw data, is not legally required to honour requests for access from independent researchers.

"The BMJ supports vaccination policy based on sound evidence," they write. "As the global vaccine rollout continues, it cannot be justifiable or in the best interests of patients and the public that we are left to just trust "in the system," with the distant hope that the underlying data may become available for independent scrutiny at some point in the future."

The same applies to treatments for COVID-19, they add. "Transparency is the key to building trust and an important route to answering people's legitimate questions about the efficacy and safety of vaccines and treatments."

What's more, the public paid for COVID-19 vaccines through vast public funding of research, and it is the public that takes on the balance of benefits and harms that accompany vaccination. "The public, therefore, has a right and entitlement to those data, as well as to the interrogation of those data by experts."

They conclude: "Pharmaceutical companies are reaping vast profits without adequate independent scrutiny of their scientific claims. The purpose of regulators is not to dance to the tune of rich global corporations and enrich them; it is to protect the health of their populations. We need complete data transparency for all studies, we need it in the public interest, and we need it now."

[Ends]

**More information:** Peter Doshi et al, Covid-19 vaccines and treatments: we must have raw data, now, *BMJ* (2022). DOI: 10.1136/bmj.o102

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