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In the pages of The BMJ a decade ago, in the middle of a different pandemic, Tamiflu (oseltamivir) was described as "the drug the world had spent billions stockpiling antivirals for influenza that had not proved effective in treating or preventing complications, hospitalisations, hospital admissions, or death. The majority of trials that underpinned regulatory approval were sponsored, unpublished, and unavailable (Tamiflu) were sponsored by the manufacturer; most were unpublished; those that were published were ghostwritten by writers paid by the manufacturer; the people hired as principal authors lacked access to the raw data, and academics who requested data from the sponsor for independent analyses were denied.[1]

The Tamiflu trials became a decade of unprecedented attention to the importance of sharing clinical trial data. Public bodies for drug company data, transparency campaigns with thousands of signatories, straightforward calls for all trials to be registered, explicit commitments from companies to share data, new data sharing platforms, and new requirements for journals to publish from medicines regulators—all promised a new era in data transparency.[2]

Progress was made, but clearly not enough. The errors of the last decade are being repeated with covid-19 vaccines and trials, despite the global rollout of covid-19 vaccines and treatments, the anonymised participant level data underlying the trials for regulatory approval are not publicly available (not accessible to researchers and the public—and are likely to remain that way for years to come). The regulatory data needed for all trials, but especially for those involving major public health interventions.

Unacceptable delay

Pfizer and BioNTech's vaccine trial was funded by the company and designed, run, analysed, and authored by Pfizer employees. The trial protocols and statistical analysis plans (documents that carried out the trial) left all the data. And Pfizer has indicated that it will not release participant level data for regulatory review until 2025, 24 months after the primary trial completion date, which is not until December 2023 (ClinicalTrials.gov as at 19 November 2021).[3]

The lack of access to data is consistent across vaccine manufacturers. Moderna says data "may be available ... with the authorization of the study results in 2022," Janssen's data will be available "upon request and subject to review once the trial is completed," and Novavax has an estimated primary completion date of 27 October 2022 (NCT04611427).

As of 31 December 2021, AstraZeneca may be ready to entertain requests for data from several of its large trials. But it has not actually obtained data could be slow going. As its website explains, "Requests may be required and can take a year or more upon full submission of the request."[4]

Underlying data for covid-19 therapeutics are similarly hard to find. Published reports of Regeneron's phase III trial of its monoclonal antibody therapy REGEN-COV likely state that participant level data will not be made available until 2023. Should the drug be approved (and not just emergency authorised), "eligibility will be considered."[5] Furthermore, the US National Institutes of Health, which funded the trial, created a new portal to share data (https://accesscovidtherapeutics.nih.gov/), but the dataset on offer is limited. An accompanying document explains: "The longitudinal data set will contain a small subset of the protocol and statistical analysis plan (SAP) datasets."

We are left with publications but no access to the underlying data on reasonable request. This is worrying for trial participants, researchers, clinicians, journal editors, policy makers, and the public. The journals that have published these primary studies have stated that they forward an awkward dilemma, which pits between making the summary findings available quickly and upholding the trend of data sharing that support timely access to data and analysis. In our view, there is no dilemma; the anonymised individual participant data from clinical trials must be made available for independent scrutiny.

Journal editors, systematic reviewers, and the writers of clinical guidelines need to generally obtain little beyond journal publication, but regulatory agencies receive far more granular data as part of the regulatory review process. Re-use of the European Medicine Agency's former executive director and chief medical officer, "relying solely on the publication of clinical trials in scientific journals as the basis of healthcare decisions is not a good idea ... Drug regulation have been aware of this limitation for a long time and routinely ask for and assess the full documentation (rather than just publications)."

Interestingly, the US Food and Drug Administration is believed to receive the most raw data but does not proactively share them. After a freedom of information request from the agency for Pfizer's vaccine data, the FDA offered to release 500 pages a month, a process that would take decades to complete, arguing (correctly) that public releasing data was slow owing to the need to first redact sensitive information. This month, however, the data remained of limited utility with various redactions aimed at protecting trial blinding. But study reports from Pfizer's vaccine trials have been available since December 2021—and missing appendices may be accessible through freedom of information requests.

Even so, anyone looking for participant level datasets may be disappointed because Health Canada and the EMA do not review or analyze the data, and it remains to be seen how the FDA responds to the court order. Moreover, the FDA is producing data slowly, and the agency has stated that it will release only the requested until the vaccines are approved, which the Moderna and Johnson & Johnson vaccines are not. Indeed, with holds the raw data, is not legally required to honour requests for access to information (FOI) requests.

Transparency and trust

As well as access to the underlying data, transparent decision making is essential. Regulators and public health bodies could do better. Such as why vaccine trials were not designed to test efficacy against infection and spread of SARS-CoV-2. Had regulators focused on this outcome, countries would have been sooner about the effect of vaccines on transmission and been able to pass accordingly.

Big pharma is the least trusted industry. At least three of the many companies making covid-19 vaccines have past criminal and civil settlements costing them billions of dollars. One pleaded guilty to fraud. Other companies have no pre-covid track record. Now the covid pandemic has made many drug companies, vaccine and vaccine manufacturers have reported tens of billions in revenue.

The BMJ opposes commercial pressures based on sound evidence. As the global vaccine rollout continues, we call for transparency and trust. Transparency is the way to achieve it, and trust is 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. Transparency is the key to achieving an all important route to answering people's legitimate questions about the efficacy and safety of vaccines and treatments and the clinical and public health policies established by them use.

Twelve years ago we called for the immediate release of raw data from clinical trials. We reiterate that call now. Data should be available when trial results are announced, published, or used to inform regulatory decisions. There is no scientific or ethical exemptions from good practice during a pandemic. The public has 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, and it is time for the interrogation of those data by experts.

Pharmaceutical companies are meaning said profits without adequate independent scrutiny of their scientific claims... The people in charge need to start to derive the trust of the global corporations and enrich them further; 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.

Footnotes

Competing interests: We have read and understood BMJ policy on declaration of interests and declare that Peter Doshi is a founder of the AllTrials campaign. PD was one of the Cochrane reviewers studying influenza antivirals beginning in 2005, who campaigned for access to data. He also helped organise the Coalition Advocating for Adequately Licensed Medicines (CALM), which called on Roche/Genentech the EMA to refrain from big pricing any covid-19 vaccines this year (Doshi P. 2021;11:2-0.7282). PD also is a member of Public Health and Pharmaceutical Medicine in Transparency, which has used the FDA to obtain the Pfizer covid-19 vaccine data. The views and opinions do not necessarily reflect the official policy or position of the University of Maryland.

Provenance and peer review: Commissioned; externally peer reviewed.

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