

Why AstraZeneca and others racing to make a COVID-19 vaccine should be more open about the process

September 16 2020, by Duncan Matthews



Credit: Nataliya Vaitkevich from Pexels

AstraZeneca [is resuming](#) clinical trials for the COVID-19 vaccine, ChAdOx1 nCoV-19, following confirmation that is safe to do so. The

trials were paused when one of the participants developed an "unexplained illness."

The pause is over, but the concerns that it raises about transparency are not. When AstraZeneca announced the pause on September 8, it [was reported](#) initially as a sign of biopharma companies taking a prudent approach to safety protocols.

This was underlined by the fact that on the same day as the announcement, the CEOs of nine biopharma companies, including AstraZeneca, signed the [We Stand With Science pledge](#) to make clear their ongoing commitment to developing and testing potential COVID-19 vaccines in accordance with high ethical standards and sound scientific principles.

In doing so, these companies had been seeking to pre-empt concerns some people have that medicines regulators [in the US](#) in particular might prematurely approve a vaccine in the face of political pressure and thereby put the public at risk.

Yet the announcement that trials had resumed came in the face of [criticism](#) from some quarters that AstraZeneca had been withholding information from the public. It announced the pause after being [questioned](#) about it by health news site STAT News and. The company gave no details about the nature of the participant's illness.

Those details were instead revealed by [STAT News](#) later the same week, which stated that AstraZeneca CEO [Pascal Soriot had elaborated](#) on the reasons behind the pause during a private conference call with investors, set up by US investment bank JP Morgan. Soriot reportedly told them the participant in question was a woman in the UK who experienced neurological symptoms consistent with the rare but serious spinal inflammatory disorder, transverse myelitis.

It was also reported to have emerged during the call that trials had already been halted once, in July, after a participant experienced neurological symptoms which it later transpired were MS and unconnected to the trial. Given the global public attention on the vaccine race, the lack of publicly available information from the company and the other partners in the project is surprising.

This is happening in a climate where many people would already be very reluctant to take a COVID-19 vaccine. Vaccine hesitancy and skepticism [was common](#) before the pandemic, and is not getting better: a third of Americans [say they may refuse](#) a vaccine, while in the UK [only half](#) of people would definitely agree to be vaccinated.

There is a [real risk](#) that lack of transparency about [clinical trials](#) might fuel vaccine skepticism and ultimately lead to large sections of the population refusing vaccination. This would impede rollout and potentially exacerbate the pandemic.

The risks of silence

A key reason for declining public confidence in vaccines is the tendency for [biopharma companies](#) to treat clinical trials data as proprietary intellectual rights that must be protected as [confidential information](#) and trade secrets. AstraZeneca [said that](#) it could not disclose further medical information on the reasons for the trial pause.

The EU [regulation](#) on clinical trials states that such information will be publicly available unless certain exceptions apply, including the need to protect commercially confidential information unless there is an overriding public interest in disclosure.

On one level, biopharma companies are legitimately protecting their commercial investments by keeping trials data confidential. But with

COVID-19, there is surely an overriding public interest in disclosure. Even before clinical trial results are submitted to a medicines agency, public disclosure should be paramount.

Also, the notion that clinical trials data should be considered proprietary information is based on the presumption that it is private finance paying for the trials. But in the case of COVID-19 vaccines, vast amounts of public money are contributing to the investment.

In the case of the Oxford-AstraZeneca vaccine, the public money involved is widely acknowledged in [official databases](#) which make clear that the trials are being funded by the University of Oxford, with the UK government having given the university an additional £65.5 million towards the project.

The vaccine was in fact co-invented by the university and spin-out [company](#) Vaccitech. AstraZeneca is involved under a licensing agreement, with responsibility for global development, manufacturing and distribution. Given that the terms of this agreement are confidential, it is difficult to comment further, but it is hard to justify confidential trials when so much public money is involved—particularly given the levels of vaccine hesitancy.

Political pressure

Coupled with this is the enormous political pressure to get vaccines approved. It has been widely reported that the US Food and Drug Administration (FDA) is being [heavily pressed](#) by the Trump administration to approve a vaccine ahead of the presidential election on November 3.

Most Americans [now think](#) the FDA may move with undue haste to approve vaccines before phase 3 trials have been concluded. This has led

FDA Commissioner Stephen Hahn [to insist](#) that the agency will not rush the process.

The FDA has also [issued recommendations](#) on developing and licensing COVID-19 vaccines, while stating that it will use an independent advisory committee to monitor industry compliance, but the voluntary nature of that initiative has failed to boost public confidence.

Even biopharma companies [acknowledge that](#) people are skeptical about the heavily politicized fast-tracked vaccine timeline. The timing of the We Stand With Science pledge is therefore significant.

But despite the pledge and the resumption of trials, AstraZeneca's public reaction to its trial problem is a sign of the private sector applying old rules to new circumstances. COVID-19 is a game-changer in terms of how the public funds clinical [trials](#) and scrutinizes vaccine safety. We need to build [public confidence](#) in vaccines and better communication is vital. Biopharma companies may not yet have come to terms with these new realities, and this risks entrenching [vaccine](#) hesitancy further.

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