

# AstraZeneca confirms strong vaccine protection after US rift

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A vial of the AstraZeneca COVID-19 vaccine, manufactured by the Serum Institute of India and provided through the global COVAX initiative, is removed from a portable cold storage box in preparation for a vaccination, in Machakos, Kenya, Wednesday, March 24, 2021. AstraZeneca's repeated missteps in reporting vaccine data coupled with a blood clot scare could do lasting damage to the credibility of a shot that is the linchpin in the global strategy to stop the coronavirus pandemic, potentially even undermining vaccine confidence more broadly, experts say. (AP Photo/Brian Inganga)

AstraZeneca insisted that its COVID-19 vaccine provides strong protection even after counting additional illnesses in its U.S. study, as the drugmaker responded to concerns raised by American officials in an unusually public rebuke that threatened to further erode confidence in the shot.

In a late-night news release Wednesday, AstraZeneca said it had analyzed more data from that study and concluded the vaccine is 76% effective in preventing symptomatic COVID-19, instead of the 79% it had reported earlier in the week.

Some experts called the new analysis reassuring and said the updated details didn't look substantially different from what was announced earlier. A peek at the full data won't come for at least another few weeks, once the Food and Drug Administration begins its own stringent review. For now, it's not clear if the new figures will be sufficient to repair the credibility in a vaccine that, despite being widely used in Britain, Europe and other countries, has had a troubled rollout.

Earlier this week, an independent panel that oversees the U.S. trial of the vaccine had accused AstraZeneca of cherry-picking data to tout the protection offered by its shot. The panel, in a harsh letter to the company and to U.S. health leaders, said AstraZeneca had left out some COVID-19 cases that occurred in the study.

The drugmaker responded that the results it reported included cases up to mid-February, as agreed in the study rules, and that it was preparing a fuller analysis of cases that had occurred since then—which it released Wednesday.

"AstraZeneca may have just been too hasty in submitting the earlier,

incomplete interim analysis rather than waiting to analyze and submit the full dataset," said Julian Tang, a virologist at the University of Leicester who was not connected to the research. He said the updated details were likely solid enough for U.S. regulators to authorize the vaccine.

Before the new results were released, Dr. Anthony Fauci, the top U.S. infectious disease expert, told reporters he hoped that when all the data was publicly vetted by the FDA, it would dispel any hesitancy caused by the spat. He predicted it would "turn out to be a good vaccine."

AstraZeneca had been counting on findings from a predominantly U.S. study of 32,000 people to help rebuild confidence in its shot, which is crucial to global efforts to end the coronavirus pandemic since it is cheap, easy to store and a pillar of the COVAX initiative aimed at bringing vaccines to low- and middle-income countries. Despite evidence from trials and in real-world use that it does protect, previous studies have turned up inconsistent data about the degree of effectiveness.

Then last week a scare over blood clots had some countries temporarily pausing inoculations. Most have since restarted after the European Medicines Agency said [the vaccine doesn't increase the overall incidence of blood clots](#), though it did not rule out a connection to some rare clots. On Thursday, Denmark [announced it would continue its suspension of the vaccine](#).

AstraZeneca's newest effectiveness calculations were based on 190 COVID-19 cases that occurred during the U.S. study, 49 more than it had included earlier in the week. The vaccine appears especially protective against the worst outcomes, with no severe illnesses or hospitalizations among vaccinated study volunteers compared to eight severe cases among those given dummy shots, the company said. It didn't provide a breakdown of the rest of the cases.

Some European authorities have questioned how protective the vaccine is in older adults. In the U.S. study, it was 85% effective in volunteers 65 and older, the company said. The study didn't turn up safety concerns.

The updated information "confirms that our COVID-19 vaccine is highly effective in adults, including those aged 65 years and over," AstraZeneca research chief Mene Pangalos said in a statement. He said the company looks forward to "the rollout of millions of doses across America."

The study hasn't ended, so additional COVID-19 cases could still accrue. AstraZeneca cautioned that 14 additional possible cases already are being examined and that could lead to further changes in the data.

The company intends to seek FDA clearance of the vaccine within a few weeks. The agency will publicly debate all the evidence with its outside advisers before making a decision.

Stephen Evans, a vaccines expert at the London School of Hygiene and Tropical Medicine, said it was difficult to understand why the dispute between AstraZeneca and U.S. officials spilled into the public. Such rifts during ongoing studies typically remain confidential.

"Given the details given here, it seems an unnecessary action to have raised concerns in public," he said. "Results fluctuate as data accumulate ... what counts will be the FDA assessment and that will be done based on scrutiny of the full data and not press releases." He said any vaccine with an efficacy rate higher than 60% is useful.

He said it was unclear why there was "a breakdown in relations" between AstraZeneca and the independent U.S. data experts monitoring the trial and worried that could undermine confidence in the vaccine.

"This vaccine is so important for global health, and the disputes do not promote global health," he said. "At least in the short term, (this) will undermine confidence both in the U.S. and more importantly in the rest of the world."

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