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Q&A

Behind the scenes of the Pfizer BioNTech covid-19 vaccine trial

Never has the spotlight been as strong on a clinical trial as that on the Pfizer BioNTech vaccine, the first approved for covid-19. **The BMJ** spoke to its lead principal investigator, Stephen Thomas

Joanne Silberner

In early November 2020, Stephen Thomas, chief of infectious diseases at SUNY Upstate Medical University, New York, became the lead principal investigator for one of the most closely watched clinical trials in history.

The US Food and Drug Administration (FDA) authorised the vaccine for emergency use on 11 December—a week after the UK made it the first in the world to be approved. The manufacturer hopes to produce 1.3 billion doses by the end of 2021.

Picked to lead

“The Pfizer trial had more than 150 sites in many countries, with tens of thousands of participants. I was one of many principal investigators. Our team here in Syracuse, New York, was one of the first sites to start enrolling in the phase III part of the trial back in July, and we enrolled a couple of hundred people. Drug companies choose one principal investigator to ask questions and put an outside set of eyes on the data and information that are submitted to the FDA. Pfizer came calling, and I was very happy that I could participate.”

Working with Pfizer

“I’m not an employee of Pfizer. Its relationship is with my university. I have not seen my pay change. It’s the same type of relationship that we have with any funder of a trial.

“I didn’t feel any pressure timewise from Pfizer though there was a sense of urgency to immediately review the data and generate questions and have a dialogue. We were in the middle of a pandemic, people in the country were dying every 30 seconds or so.”

Accuracy, not speed

“There was always the feeling of moving quickly, but not rushing. If you rush, bad things can happen. We were never asked to, and we never did, rush through anything.”

The view from the ground

“Our hospital had a peak of covid-19 cases in April and May, but we had a good summer. By the end of October, however, things got really, really bad and we became a hot spot.

“The trial team has been sprinting for a long time. They’ve been working incredibly long hours, and there really hasn’t been much of a break. At the same time, they’re living in a hot spot of covid-19. Many of our investigators are physicians who work in the

hospital, so they’re also taking care of patients. Everyone’s concerned about whether they’re going to get infected. And then we all try to go home to our families, and we’re concerned about them.”

On participants given placebo

“You don’t want to deny those people access to the vaccine, because one of the reasons that they were enrolled is because they were at risk of infection or at risk of a bad outcome from infection. On the other hand, you also need to continue the trial till its end. And it’s a two year study. We need to keep a placebo component and blinding going.

“Still, we’ve got to meet the needs of these volunteers who received placebo. There are now groups of people who would be vaccinated under the emergency usage authorisation. Once their number comes up within their community and the vaccine is accessible, those people are provided the opportunity to unblind. And if they did receive placebo, then we offer them vaccination—and we’d continue to follow them and do the other trial activities that we planned on doing for the rest of the two year period.”

Working at the dinner table

“Right around dinnertime, my email would ping and my wife would look at me. We’ve been married for a while and she’d grin and say ‘you can go, you can go.’ Overall, it’s been quite a long year.”

Doing it again

“As stressful and as fatiguing as it has been at times, my team and my university and my community feel privileged and proud to have participated in trying to help develop one of the potential solutions to this pandemic. If you don’t want to step up and contribute in a situation like this, what’s the point? I would absolutely do it again. I’d just hope for a little bit of a break beforehand.”