Flouting all standards, Russia plans to release early COVID-19 vaccine data



Enlarge / MOSCOW, RUSSIA – AUGUST 14, 2020: Alexander Gintsburg, director of the Gamaleya Scientific Research Institute of Epidemiology and Microbiology of the Russian Healthcare Ministry that produces a COVID-19 vaccine.

reader comments

95 with 58 posters participating

Share this story

Covid-19 Coverage

View more stories

A top Russian researcher behind the Sputnik V coronavirus vaccine defended using the vaccine before testing was complete and said he plans to release clinical trial data early—so early, in fact, the data is unlikely to be interpretable.

Alexander Gintsburg, head of the Gamaleya Institute that developed Sputnik V, laid out his thoughts on the vaccine and the pandemic in an interview with Reuters published Tuesday.

“People are dying just like during a war,” Gintsburg said as he sat in his wood-paneled office in Moscow, holding a crystal model of a coronavirus. “But this fast-tracked pace is not synonymous—as some media have suggested—with corners being cut. No way.”

Russian President Vladimir Putin announced in August that the country had granted the world’s first regulatory approval for a vaccine against the pandemic coronavirus, despite not even starting Phase III clinical trials, which typically test safety and efficacy of a vaccine in tens of thousands of people. The approval drew quick criticism from health experts, who saw it as a dangerous political stunt to give the appearance that Russia was ahead in the race to develop a vaccine.

Russian roulette

But Gintsburg defended the approval on ethical grounds, saying, “The choice was between giving people the opportunity to protect themselves, or letting them play roulette with this deadly infection.”

The health ministry has since given doses of Sputnik V to about 400 members of the general public not enrolled in a

clinical trial, according to Reuters. Initially, government figures had suggested millions of people might be inoculated.

Meanwhile, Russian researchers have gone ahead with the standard Phase III trials. On September 9, researchers vaccinated the first 5,000 trial participants and have planned to vaccinate more than 40,000 in all. Gintsburg said that researchers will release data from those participants after just six weeks (42 days) of monitoring. That would mean the first data would be ready by October 21, and Gintsburg expects it to be released in late October or November.

Such early data is unlikely to be informative or even interpretable, given the small batch of participants and the short follow-up. Globally, there are several vaccines currently in Phase III trials, including some that began in June and July. None of the researchers and companies running those trials have yet to release data, and most of their progress is measured by cases of COVID-19 in participants (both those vaccinated and those given a placebo) rather than an arbitrary time point.

Too short

For instance, Pfizer and its partner BioNTech began a Phase III trial of a COVID-19 vaccine in July. The companies have said they will conduct a first interim analysis when 32 people in the trial test positive for the virus. Moderna, which also started a Phase III trial in July, said it will perform an interim analysis when there are 53 cases in trial participants. AstraZeneca, which started a Phase III trial of a vaccine with the University of Oxford even before July, is waiting for 75 cases before doing an interim analysis.

If interim analyses are extremely positive, vaccine developers *could* release the data and even stop trials early. To do that, they would need to see that most of the COVID-19 cases in study participants were those in the placebo group rather than

the vaccinated group, suggesting that the vaccine protected against disease. But it’s more likely that the data will be harder to interpret early on. And releasing “promising” but not conclusive data could easily lead to over-interpretation.

Stopping trials early is even riskier. Once a trial is ended, it’s very difficult to assess exactly how well a vaccine works. There are no longer trial controls or placebo groups for comparison.

Still, President Donald Trump has pushed for interim analyses to be done as soon as possible and for a vaccine to be rolled out to the public by November 3, election day. Experts say it’s extremely unlikely that a vaccine would be ready in the United States before the election. Additionally, the Food and Drug Administration has worked to tighten requirements for any vaccine to be authorized based on early data for interim analyses (though the White House may quash those stricter guidelines).

But according to Gintsburg’s timeline, Russia could have data on Sputnik V in time for November 3.

“For me, for example, it is too short,” Gintsburg said of the 42-day analysis. “But for people who are interested in how things are going, it is already too long.”

https://arstechnica.com/?p=1710448