

Russia Ignores Requests to Share Controversial Coronavirus Vaccine Data

Russia's Gamaleya Institute has not responded to multiple requests to share more information on the results of clinical trials published in *The Lancet*.

By [Jake Cordell](#)

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Russia became the first country in the world to approve a Covid-19 vaccine in August — a move which raised significant concerns over fast-tracking the usual scientific process. **Sofia Sandurskaya / Moskva News Agency**

Russian scientists have not shared the data behind controversial clinical trial results into a coronavirus vaccine published in leading medical journal *The Lancet* a month ago, researchers who requested the information told The Moscow Times.

A group of 37 scientists from 12 countries have now signed an [open letter](#) questioning the published results into Russia's Sputnik V vaccine, citing apparent duplications of data

concerning antibody responses among participants given different formulations of the vaccine. They say such duplication is “[highly unlikely](#)” and raised the possibility of data manipulation.

Related article: [Leading Scientists Question 'Highly Improbable' Russian Vaccine Results Published in Lancet](#)

Russia’s state research center responsible for developing the vaccine, the Gamaleya Institute, has [disputed the claims](#). And in a [reply](#) published Sept. 21 by The Lancet, the Institute said it would share the raw data if other researchers and scientists sent them a formal request. The original publication only included results in diagram form.

But the Gamaleya Institute has ignored multiple public calls and at least two official proposals requesting access to the data, according to the group of researchers who first raised concerns.

In emails seen by The Moscow Times, Raffaele Calogero, a professor at the University of Turin’s bioinformatics and genomics unit sent official requests to Denis Logunov, the study’s lead author and deputy research director of the Gamaleya Institute, on Sept. 23 and Sept. 30 asking for the “raw anonymized data.”

“The data will be used by me and other authors of the correspondence letter to reconstruct the overall figures described in your paper and to clarify the concerns described,” Calogero told Logunov, attaching the formal signed request.

Logunov has not responded to either email or acknowledged that he has received them, Calogero said. The emails and attached letter were sent to Logunov’s official correspondence address for the study, which was published by The Lancet. Logunov did not respond to The Moscow Times’ requests for comment.

'Very strange'

Enrico Bucci, a biology professor at Temple University in the U.S. who first highlighted possible data duplication said Russia’s public response failed to address his concerns and that he does not expect Russia to become “more transparent.”

“Their answer was mostly a repetition of what’s in the original paper — even the wording,” he told The Moscow Times. “Most of our questions were left unaddressed and, chiefly, they did not provide us with the required data. We are in the same position as before.”

He added: “We don’t know whether they will answer. They didn’t in the past, and they are saying that they reserve the final decision over who to let have the data, which is also very strange. This is contrary to the standards of science, where we have to be open.”

The critics say they need the data to properly scrutinize the published results and assess their veracity.

One of the letter’s signatories, Konstantin Andreev of Northwestern University in the U.S. [told](#) the Meduza news outlet the probability of achieving the results which were published was just 1.4%. Bucci said that even using the most favorable possible assumptions to fill in data gaps,

he could not find a “high probability” of reproducing the Russian results in his statistical models.

“We need to go into this,” he said. “And we cannot unless they provide us with the details and data we requested.”

Bucci also criticized The Lancet for its role in the study. “We had a journal publish something without access to the data or without providing the reader access to the data.”

Fast-track approval

The results in question — non-randomized Phase 1/2 clinical trials of Russia’s Sputnik V vaccine — were [originally published](#) in The Lancet on Sept. 4. The study involved 76 volunteers, all of whom developed an immune response and reported no serious side effects.

Russian authorities loudly cheered the findings, including the fact that the study was published in The Lancet — seen as the world’s leading medical journal. On the day the study was published, Kirill Dmitriev, CEO of the Russian Direct Investment Fund (RDIF), which is funding the vaccine development, said the study was “the final answer in the round of questions directed against Russia” over the vaccine’s development.

Related article: [Moscow Expects Year-End Coronavirus Vaccine Rollout](#)

In a [lengthy article](#) published in English, RDIF added that the study concluded Sputnik V will work in 100% of cases, appeared more effective in producing an antibody response than other vaccines under development, and raised questions about the methods and approach used to develop the AstraZeneca/Oxford vaccine, seen as one of the frontrunners in the global vaccine race.

Russian President Vladimir Putin [approved](#) the Sputnik V vaccine on Aug. 11 — three weeks before the Phase 1/2 results had been published and months before results of the [large-scale Phase 3 trials](#) which are usually needed before drugs are given regulatory approval — making Russia the [first country](#) in the world to green-light a vaccine for the virus which has claimed more than a million lives around the world.

The scientists stress that their concerns over the published research do not necessarily mean data in the study was manipulated or that the vaccine is ineffective or could lead to side effects — questions large-scale phase 3 medical trials, [currently underway](#), are designed to answer.

“This vaccine might work,” said Bucci. “But what cannot work is this way of proceeding in science.”

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