# News in focus

expected in the coming months. Lundgren's trial, announced on 4 August, aims to enrol 1,000 people with COVID-19. Another large trial, sponsored by the NIH and Regeneron, a biotechnology company in Tarrytown, New York, launched on 6 July and will test a cocktail of two antibodies against SARS-CoV-2. Results are expected in late September.

Although these antibodies target the same virus, each interacts with SARS-CoV-2 differently: some will bind more strongly to the virus than will others, for example, or will target sites on its surface that shut the virus down more efficiently. And although antibodies are a natural means of defence, there are safety concerns, Lundgren notes. Researchers will be looking out for 'antibody-dependent enhancement', a phenomenon in which some antibodies can help viruses to gain entry into human cells, rather than prevent infection. A large trial is needed to settle the matter convincingly, Lundgren says.

# OUTRAGE OVER Russia's Fast-track Coronavirus Vaccine

Scientists worry about the immunization's safety because it hasn't been tested in large trials.

### By Ewen Callaway

ussian President Vladimir Putin announced on 11 August that the country's health regulator had become the first in the world to approve a coronavirus vaccine for widespread use – but scientists globally have condemned the decision as dangerously rushed. Russia hasn't completed large trials to test the vaccine's safety and efficacy, and rolling out an inadequately vetted vaccine could endanger people who receive it, researchers say. It could also impede global efforts to develop quality COVID-19 immunizations, they suggest. "That the Russians may be skipping such measures and steps is what worries our community of vaccine scientists. If they get it wrong, it could undermine the entire global enterprise," says Peter Hotez, a vaccine scientist at Baylor College of Medicine in Houston, Texas.

"This is a reckless and foolish decision. Mass vaccination with an improperly tested vaccine is unethical. Any problem with the Russian vaccination campaign would be disastrous both through its negative effects on health, but also because it would further set back the acceptance of vaccines in the population," said Francois Balloux, a geneticist at University



Russian President Vladimir Putin receives a report about the coronavirus vaccine.

College London, in a statement distributed by the UK Science Media Centre.

In his announcement. Putin said that the Russian regulator had approved a COVID-19 vaccine developed by the Gamaleva Research Institute of Epidemiology and Microbiology in Moscow, even though phase III trials of the vaccine had yet to be completed. Such trials involve giving thousands of people a vaccine or a placebo injection, and then tracking them to see whether the vaccine prevents disease. The tests also allow researchers to confirm the vaccine's safety and look for rare side effects that might not have been observed in smaller. earlier-stage trials. Russian health-care minister Mikhail Murashko said at a government briefing that the vaccine would be gradually introduced to citizens, starting with health workers and teachers.

More than 200 COVID-19 vaccines are in development worldwide and several are already in phase III trials, with more front runners slated to begin theirs soon. But researchers think that even the earliest of those vaccines will not be approved for months.

## Lack of data

The Gamaleya vaccine has been given to 76 volunteers as part of two early-stage trials listed on ClinicalTrials.gov, but no results from those trials or other preclinical studies have been published, and little else is known about the experimental vaccine.

According to the ClinicalTrials.gov listings, the vaccine, which is given in two doses, is made of two adenoviruses – viruses that cause a range of illnesses, including colds – that express the coronavirus's spike protein. The first dose contains an Ad26 virus – the same strain as is used in an experimental vaccine being developed by pharmaceutical company Johnson & Johnson of New Brunswick, New Jersey, and its subsidiary Janssen. The second, 'booster' dose is made of an Ad5 virus, similar to the one in an experimental jab being developed by CanSino Biologics in Tianjin, China.

According to the vaccine's Russian-language registration certificate, 38 participants who received one or two doses of the vaccine had produced antibodies against SARS-CoV-2's spike protein, including potent neutralizing antibodies that inactivate viral particles. These findings are similar to the results of early-stage trials of other candidate vaccines. Side effects were also similar, such as fever, headache and skin irritation at the site of injection.

Hotez expects that the Gamaleya vaccine will elicit a decent immune response against SARS-CoV-2. "The technical feat of developing a COVID-19 vaccine is not very complicated," he says. "The hard part is producing these vaccines under quality umbrellas – quality control and quality assurance – and then assuring the vaccines are safe and actually work to protect against COVID-19 in large phase III clinical trials."

But little is known about phase III trial plans for the Gamaleya vaccine. "I simply haven't managed to find any published details of a protocol," says Danny Altmann, an immunologist at Imperial College London. He hopes the trial is closely tracking the immune responses of participants and looking out for any side effects.

The head of a Russian government-owned investment fund said the vaccine would go through phase III testing in the United Arab Emirates, Saudi Arabia and other countries, according to the state-owned TASS Russian News Agency. The official said that purchase requests for one billion doses had been received from 20 countries in Latin America, the Middle East, Asia and elsewhere, and that manufacturing capacity was in place to produce 500 million doses, with plans for expansion.

#### 'Ridiculous authorization'

Altmann is concerned that the vaccine could cause people who receive it and are then infected with SARS-CoV-2 to experience an exacerbated form of disease that occurs when antibodies generated by a vaccine carry the virus into cells. Another problem could be an asthma-like immune reaction that became an issue with some experimental vaccines against the related virus that causes SARS (severe acute respiratory syndrome). To spot these reactions, researchers would have to compare results from thousands of people who received a vaccine or placebo and then might have been exposed to SARS-CoV-2.

"It's ridiculous, of course, to get authorization on these data," says Svetlana Zavidova, head of Russia's Association of Clinical Trials Organizations in Moscow, which works with international pharmaceutical companies and research organizations. Without a completed phase III trial, Zavidova also worries that it will not be clear whether the vaccine prevents COVID-19 or not – and it will be difficult to tell whether it causes any harmful side effects, because of gaps in how Russia tracks the effects of medicines. "Our system for safety monitoring, I think, is not the best," she says.

Zavidova also worries the vaccine's approval will be "very harmful" for efforts to run clinical trials of other COVID-19 vaccines and other medicines in Russia.

"Not sure what Russia is up to, but I certainly would not take a vaccine that hasn't been tested in Phase III," tweeted Florian Krammer, a virologist at the Icahn School of Medicine at Mount Sinai in New York City. "Nobody knows if it's safe or if it works. They are putting [health-care workers] and their population at risk."

# **CONFERENCES FAILING TO PROTECT LGBT+ RESEARCHERS**

Promoting equity, diversity and inclusion at meetings requires more than a code of conduct, analysis finds.

#### **By Smriti Mallapaty**

yesha Tulloch was reluctant to go to a conservation-biology conference in Malaysia, where laws discriminate against people of specific sexual orientations. "It came as quite a shock to me that the discipline I felt was the most accepting and tolerant toward the queer community would choose to have a conference in a place that's really not queer friendly," says Tulloch, a conservation scientist at the University of Sydney in Australia.

She did end up going to the meeting in Kuala Lumpur last year, organized by the Society for Conservation Biology (SCB), but she wondered whether the society's processes for fostering a diverse and inclusive meeting had failed when it chose that location.

Tulloch went on to analyse policies and practices for supporting equity, diversity and inclusion around gender and sexual orientation, performing the first investigation of this kind. She looked at 30 ecology and conservation conferences held since 2009 and reported the results in Nature Ecology and Evolution on 3 August (A. I. T. Tulloch Nature Ecol. Evol. http://doi.org/d6nt; 2020). Tulloch found that about half of the events had codes of conduct promoting equity, diversity and inclusion. Those conferences were more likely than others to have initiatives that discouraged overt discrimination, such as a point of contact to report misconduct and facilities for breastfeeding and childcare.

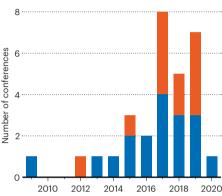
#### No guarantee

But having a code did not always lead to initiatives that reduced implicit biases and barriers to participation, says Tulloch. For instance, conferences with a code were no more likely to advertise pronoun guidelines for name badges, select diverse speakers or choose locations safe for people of all genders and sexual orientations than were events without a code. Almost 40% of the conferences were held in locations where laws and societal norms discriminate against people of specific genders or sexual orientations (see 'Location, location'). And only two provided information on their websites about how they planned to ensure participants' general safety, for example by providing shuttle buses for safe transit between venues.

### LOCATION, LOCATION

Some 40% of conservation and ecology conferences over the past decade were held in locations where laws and societal norms discriminate against people of specific genders or sexual orientations.





The analysis shows that codes of conduct have limitations, and putting a policy in place is not enough, says Lisa Kewley, an astrophysicist at the Australian National University in Canberra, who advocates for diversity at astronomy conferences.

But others say the analysis assumes that codes of conduct are supposed to promote diversity and inclusion, which is not necessarily their intended purpose. Codes are designed to protect against harassment and to clarify which behaviours will not be tolerated at a meeting, says Robyn Klein, a neuroimmunologist at Washington University in St. Louis, Missouri. They are not meant to have any bearing on diversity of speakers, she says.

Leslie Cornick, a conservation ecologist at the University of Washington Bothell who was chair of the 2019 SCB congress in Malaysia but had no part in deciding the location, agrees that codes of conduct are not necessarily intended to foster diversity, equity and inclusion, although they are a statement of values.

Cornick also notes that when choosing conference locations, organizers have to consider all members, including those who cannot afford to travel long distances.

But Tulloch says that codes are in place to address identity-based discrimination, which includes ensuring that participants have equal access. "The idea that a code is only there to prevent overt misconduct is outdated and incorrect," she says.