COVID-19 VACCINES

Summary of Study Design, Outcomes, Status

McDougall Scientific
INSIGHTS YOU CAN TRUST

SPharm

References

All Vaccines presented in this report are either in Phase 3 or authorized for emergency use. All data and summaries in this report have been referenced from the following sources:

NIH National Institutes of Health
Turning Discovery Into Health
ClinicalTrials.gov

ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.

https://clinicaltrials.gov/

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

The Regulatory Affairs Professionals Society (RAPS) is the largest global organization of and for those involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics and nutritional products.

https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker

The New York Times

Here is the status of all the vaccines that have reached trials in humans, along with a selection of promising vaccines still being tested in animals.

https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

CNN health

Explore news, articles and information on nutrition, medicine, diseases and healthy living.

https://www.cnn.com/2020/11/24/health/covid-vaccines-design-explained/index.html

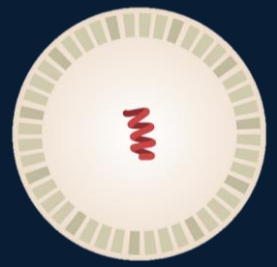
Health Canada

Health Canada is the department of the Government of Canada that is responsible for the country's federal health policy

https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/covid-19-vaccine-treatment.html

Vaccine Types

The vaccines portrayed in this report represent the following Vaccine Types.

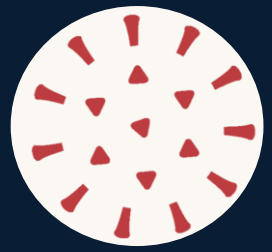


GENETIC VACCINES

mRNA vaccines are the newest approach. They use genetic material called messenger RNA, a kind of genetic software that instructs cells to make a piece of the coronavirus spike protein. That will get the attention of the immune system. The mRNA is coated in soft fatty lipids to protect it.

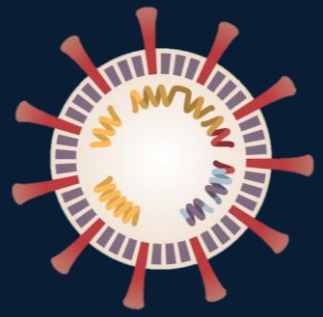
VIRAL VECTOR VACCINES

Vector vaccines use another virus to carry in the genetic instructions to make the spike protein. For coronavirus they all use adenoviruses, a type of common cold virus. They attach to cells and inject DNA that tells the cells to make coronavirus spike protein.



PROTEIN-BASED VACCINES

Protein vaccines just get little pieces of the target virus circulating in the system for the immune system to find and recognize. Instead of using the human body as the vaccine factory, genetically engineered insect viruses are used to infect moths, whose cells then produce the pieces of coronavirus spike protein. These are harvested and made into a vaccine.



INACTIVATED VACCINES

Whole inactivated virus vaccines take longer to make because batches of the coronavirus must first be grown and then killed using a chemical or heat, and then made into a vaccine that can be injected to elicit an immune response.

Promising Covid-19 Vaccines

PFIZER, BIONTECH

MRNA-BASED VACCINE

JOHNSON & JOHNSON

NON-REPLICATING VIRAL VECTOR

SINOVAC

INACTIVATED VACCINE

BHARAT BIOTECH; NATIONAL INSTITUTE OF VIROLOGY

INACTIVATED VACCINE

MODERNA

MRNA-BASED VACCINE

NOVAVAX

NANOPARTICLE VACCINE

GAMALEYA RESEARCH INSTITUTE, ACELLENA CONTRACT DRUG RESEARCH (RUSSIA)

NON-REPLICATING VIRAL VECTOR

MEDICAGO; GSK; DYNAVAX

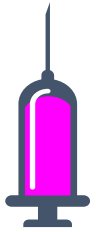
PROTEIN-BASED VACCINE

THE UNIVERSITY OF OXFORD; ASTRAZENECA; IQVIA

REPLICATION-DEFICIENT VIRAL VECTOR VACCINE

CANSINO BIOLOGICS

RECOMBINANT VACCINE



WUHAN INSTITUTE OF BIOLOGICAL PRODUCTS; CHINA NATIONAL PHARMACEUTICAL GROUP, (SINOPHARM)

INACTIVATED VACCINE

Candidate	Mechanism	Trial Phase	Institution
BNT162	**Genetic Vaccine:** mRNA-based vaccine *Vaccines that deliver one or more of the coronavirus's own genes into our cells to provoke an immune response.*	Phase 3	Multiple study sites in Europe and North America

As of Dec 2nd, 2020, the Uk has authorized this vaccine for emergency distribution. Pfizer and BioNtech are collaborating to develop BNT162, a series of vaccine candidates for COVID-19. BNT162 was initially four candidates developed by BioNTech, two candidates consisting of nucleoside modified mRNA-based (modRNA), one of uridine containing mRNA-based (uRNA), and the fourth candidate of self-amplifying mRNA-based (saRNA). Pre-clinical results of the modRNA candidate BNT162b2 posted to the pre-print server *bioRxiv* showed the vaccine had "protective anti-viral effects in rhesus macaques, with concomitant high neutralizing antibody titers and a TH1-biased cellular response in rhesus macaques and mice." The companies have selected BNT162b2 to move forward in a Phase 2/3 trial.

Study Design/Trials	A Phase 1/2 trial in the US and Germany of 200 healthy participants between aged 18-55 years, with a vaccine dose range of 1 µg to 100 µg is currently recruiting (NCT04380701) as is a Phase 2/3 trial of about 32,000 healthy participants (NCT04368728) Pfizer and BioNTech are also planning a combined Phase 1/2 trial of 160 participants between 20-85 years old (NCT04588480).
Outcomes	On 9 November, Pfizer and BioNTech announced interim results by press release of 94 Phase 3 trial participants, which showed BNT162b2 was more than 90% effective in protecting participants who had never been infected with SARS-CoV-2 at 7 days after the second dose. Those results are backed up by Phase 1 data published in *The New England Journal of Medicine* showing similar immunogenicity between BNT162b1 and BNT162b2 but fewer adverse effects with BNT162b2. Another study of Phase 1/2 data for BNT162b1 was published in the journal *Nature*. Robust immunogenicity was seen after vaccination at all three doses (10 µg, 30 µg and 100 µg). Adverse events were elevated at the highest dose; therefore, participants did not receive a second dose at that level. Participants in Phase 1/2 trials who received two doses between 1 and 50 µg of BNT162b1 had "robust RBD-specific antibody, T-cell and favourable cytokine responses," according to a paper published in *Nature* on 30 September.
Status	In the US, Pfizer and BioNTech have requested that the FDA issue an EUA for BNT162b2; an advisory committee meeting is scheduled for 10 December. BNT162b1 and BNT162b2 received FDA Fast Track designation for BNT162b1 and BNT162b2. The companies requested conditional marketing authority from EMA on 1 December; EMA's rolling review of BNT162b2 could accelerate that authorization. In Australia, BNT162b2 received provisional determination from Australia's Therapeutic Goods Administration (TGA), which is the first step on the road for approval for the vaccine in the country. **Regulatory Actions**: BNT162b was authorized by the Medicines and Healthcare products Regulatory Agency (MHRA) for use in the UK on 2 December after a rolling review of vaccine data submitted by Pfizer and BioNTech. On December 9, 2020 Health Canada authorized the use of this Vaccine
Transport	MRNA is very fragile so it's encased in lipid nanoparticles -- a coating of a buttery substance that can melt at room temperature. That's why Pfizer's vaccine must be kept at ultracold temperatures of about minus 100 degrees F (minus 75 degrees C). That means special equipment is needed to transport and store this vaccine.

moderna

Candidate	Mechanism	Trial Phase	Institution
mRNA-1273	**Genetic Vaccine:** mRNA-based vaccine *Vaccines that deliver one or more of the coronavirus's own genes into our cells to provoke an immune response.*	Phase 3	Kaiser Permanente Washington Health Research Institute
mRNA-1273 was developed by Moderna. The vaccine contains genetic instructions for building a coronavirus protein, known as spike. When injected into cells, the vaccine causes them to make spike proteins, which then get released into the body and provoke a response from the immune system.			

Study Design/Trials	A Phase 3 trial of 30,000 participants at high risk for SARS-CoV-2 infection is underway. Participants will receive a 100 µg dose of mRNA-1273 or placebo and then be followed for up to 2 years (COVE trial; NCT04470427). Moderna posted the full trial protocol for COVE on 17 September. Previously, a Phase 1 trial (NCT04283461) of 105 healthy participants provided the basis for Moderna's investigational new drug application (IND), which was successfully reviewed by the FDA and set the stage for Phase 2 testing. A Phase 2 trial of 600 healthy participants evaluating 25 µg, 100 µg, and 250 µg dose levels of the vaccine was completed. (NCT04405076).
Outcomes	Human studies - In a primary efficacy analysis of the Phase 3 COVE trial released on 30 November, which has not been peer reviewed, Moderna said the vaccine was 94.1% effective based on 196 cases of COVID-19 in the trial. Of these, 185 cases were in the placebo group and 11 cases were in the vaccine group. All 30 cases of severe COVID-19 were in the placebo group, and 1 participant in the placebo group died from COVID-19. Previously, Moderna reported mRNA-1273 had an efficacy of 94.5% based on 95 participants in the trial. In addition, Phase 1 data published in the *New England Journal of Medicine* showed mRNA-1273 successfully produced neutralizing antibody titers in 8 participants who received either 25 µg or 100 µg doses. The response was dose dependent in 45 participants across 25 µg, 100 µg, and 250 µg dose levels. In participants with available antibody data, neutralizing antibody titers were on par with what has been seen in convalescent sera from people who have successfully fought off COVID-19. The vaccine also appears to be safe for older adults, with participants who received two 25 µg or 100 µg doses of the vaccine experiencing mild or moderate effects consisting of fatigue, chills, headache, myalgia, and injection site pain, according to data from the Phase 1 trial published in the *New England Journal of Medicine*.
Status	Moderna requested that the FDA issue an EUA for mRNA-1273 on 30 November; an advisory committee meeting is scheduled for 17 December. Moderna requested conditional marketing authorization from EMA for mRNA-1273 on 1 December. On 12 May, the FDA granted Fast Track designation to mRNA-1273. A Phase 3 trial of the vaccine is underway, which is being funded by Operation Warp Speed. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has begun a real-time review of mRNA-1273, which will allow a quicker approval process for the vaccine. Health Canada has this candidate under review as well as of October 12, 2020.
Transport	Moderna has come up with a different formulation for the lipid nanoparticles to protect the mRNA in its vaccine. Its vaccine can be shipped at minus 20 degrees C (minus 4 degrees F) and can be kept stable for 30 days at 2 degrees to 8 degrees C (36 to 46F), the temperature of a standard home refrigerator.

Candidate	Mechanism	Trial Phase	Institution
AZD1222	**Viral Vector Vaccine:** Vaccines that contain viruses engineered to carry coronavirus genes. Some viral vector vaccines enter cells and cause them to make viral proteins. Other viral vectors slowly replicate, carrying coronavirus proteins on their surface.	Phase 3	The University of Oxford, the Jenner Institute
AstraZeneca and University of Oxford are developing AZD1222 (previously ChAdOx1), a chimpanzee adenovirus vaccine. The team has previously developed a MERS vaccine. In India, the candidate is being jointly developed by the Serum Institute of India and AstraZeneca, and goes by the name Covishield. Preclinical data on the pre-print server *bioRxiv* showed a significantly reduced viral load and "humoral and cellular immune response."			

Study Design/Trials	A Phase 1/2 (NCT04324606) single-blinded, multi-center study of 1,090 healthy adult volunteers aged 18-55 years with four treatment arms is active, but not recruiting. A Phase 3 trial (NCT04516746), for which AstraZeneca released the clinical study protocol, is underway and has enrolled more than 40,000 participants. An inhaled version of the vaccine candidate is being tested in a small trial of 30 people.
Outcomes	An interim analysis of Phase 3 trial results announced by the University of Oxford and AstraZeneca of 131 cases indicates the AZD1222 has an efficacy of 70.4% across two dosing regimens. The dosing regimen that used a half dose for the initial administration and a full dose for the second administration had an effectiveness of 90%, while the regimen that used two full doses was 62% effective. So far, there has been one death in a Phase 3 trial in Brazil, which was confirmed by the Brazilian National Health Surveillance Agency (Anvisa). Preliminary results from the Phase 1/2 trial published in *The Lancet* showed the vaccine candidate had an "acceptable safety profile" with most patients demonstrating an antibody response after one dose and all patients showing a response after two doses.
Status	The AstraZeneca trials are funded in part by BARDA and Operation Warp Speed. IQVIA announced they are partnering with AstraZeneca to advance clinical trials for the vaccine. Phase 3 trials are being conducted in the United States and in study sites in India, but were put on hold following a serious adverse event. Trials have since resumed. EMA's human medicines committee (CHMP) has started a rolling review of AZD1222 to reduce the amount of time before a decision is made on safety and effectiveness, as has Health Canada as of October 1st. In Australia, the Australian Therapeutic Good Administration (TGA) granted AZD1222 provisional determination, the first step in the process for approval. The Medicines and Healthcare products Regulatory Agency (MHRA) has also begun an accelerated review of AZD1222 in Britain.
Transport	It's a cheaper way to make vaccines -- but slower than using RNA. The company has pledged to make its vaccine available inexpensively to countries around the world. The vaccine can be kept stable for six months at standard refrigerator temperatures.

Candidate	Mechanism	Trial Phase	Institution
JNJ-78436735 (formerly Ad26.COV2.S)	**Non-replicating viral vector**	Phase 3	Johnson & Johnson

Johnson & Johnson is developing JNJ-78436735 (formerly known as Ad26.COV2.S), using their AdVac and PER.C6 systems, which were also used to develop the company's Ebola vaccine. The work is being done in J&J's Janssen Pharmaceuticals division. In partnership with BARDA, J&J has committed to investing more than $1 billion in vaccine research and development. JNJ-78436735 is a part of Operation Warp Speed.

Janssen's coronavirus vaccine is a recombinant vector vaccine. It uses an adenovirus but this one does infect humans. It is a genetically engineered version of adenovirus 26, which can cause the common cold but the gene tinkering has disabled it. It also delivers the genetic instructions to make spike protein.

Study Design/Trials	A randomized, double-blind, placebo-controlled, Phase 1/2a study of recombinant JNJ-78436735 in 1,045 healthy participants 18-55 years of age, and adults 65 years or older. Study sites are planned in the U.S. and Belgium NCT04436276). The Phase 3 ENSEMBLE trial will enroll up to 60,000 participants in the United States and internationally (NCT04505722). On 23 September, J&J released the study protocol for the ENSEMBLE trial. A Phase 3 two-dose test of JNJ-78436735, called ENSEMBLE 2, is being evaluated in up to 30,000 participants and will run alongside ENSEMBLE (NCT04614948).
Outcomes	Results from the Phase 1/2a study in humans posted to the pre-print server *MedRxiv* found a single dose of the vaccine showed immunogenicity and a good safety profile. In animal studies, researchers reported in a paper published in *Nature* that a single injection of JNJ-78436735 "induced robust neutralizing antibody responses and provided complete or near-complete protection in bronchoalveolar lavage and nasal swabs following SARS-CoV-2 challenge," in rhesus macaques, while another paper published in *Nature Medicine* indicated the vaccine protected against severe disease when tested in hamsters.
Status	The ENSEMBLE trial was on hold pending a review of an adverse event a participant developed in one of the study arms, but J&J has been cleared to resume the trial in the U.S. and Brazil after the Independent Data Safety and Monitoring Board recommended the trial resume recruitment. J&J said it plans to begin testing its vaccine in adolescents "as soon as possible." Australia's Therapeutic Goods Administration (TGA) has given JNJ-78436735 provisional determination, which is the first step towards approval in the country. In August, the federal government agreed to pay $1 billion for 100 million doses if the vaccine is approved. The European Union reached a similar deal on Oct. 8 for 200 million doses. Health Canada has this candidate under review as well as of November 27, 2020. The company is aiming for production of at least a billion doses in 2021.
Transport	It's a one-shot vaccine but on November 16, 2020 Johnson & Johnson started a two-dose, Phase 3 trial in Britain, because there's some evidence that two doses provide better protection.

NOVAVAX
Creating Tomorrow's Vaccines Today

Candidate	Mechanism	Trial Phase	Institution
NVX-CoV2373	Protein-Based Vaccine: Nanoparticle vaccine	Phase 3	Novavax

Maryland-based **Novavax** makes vaccines by sticking proteins onto microscopic particles. They use virus-like nanoparticles as a base and cover them with genetically engineered pieces of the coronavirus spike protein. This is also a tried and true vaccine approach. They've taken on a number of different diseases this way; their flu vaccine finished Phase 3 clinical trials in March. The company launched trials for a Covid-19 vaccine in May, and the Coalition for Epidemic Preparedness Innovations has invested $384 million in the vaccine.

Study Design/Trials	Novavax announced in March that it has produced a stable, prefusion protein nanoparticle vaccine candidate for COVID-19. A Phase 1/2 trial evaluating NVX-CoV2373 began on 25 May **Trials**: A randomized, observer-blinded, placebo-controlled trial of 130 healthy participants 18 to 59 years of age is being conducted at two sites in Australia. Patients will receive a two-dose regimen of 5 µg or 25 µg of NVX-CoV2373 with or without Novavax's Matrix-M adjuvant (NCT04368988). A Phase 2b trial is underway in South Africa, which includes two cohorts: a group of 2,665 healthy adults and a group of 240 adults who are HIV positive (NCT04533399).
Outcomes	Phase 1 trial participants who received the vaccine developed an antibody response at multiple dose, according to data published in the *New England Journal of Medicine* in the *New England Journal of Medicine*. NVX-CoV2373 also has a favorable safety profile, according to the company.
Status	Novavax has received Fast Track Designation from the FDA for NVX-CoV2373. On May 11, CEPI announced they had provided Novavax with an additional $384 million towards the development and manufacturing of NVX-CoV2373. Novavax plans to manufacture 1 billion doses of NVX-CoV2373 by 2021 as part of their recent acquisition of Praha Vaccines. Novavax was awarded a $60 million US Department of Defense contract towards manufacturing NVX-CoV2373, according to a company press release, and another $1.6 billion from Operation Warp Speed if the candidate is effective in clinical trials. The candidate is officially begun a Phase 3 trial in the United Kingdom, which will evaluate the vaccine in up to 10,000 participants, the company said in a press release. It is expected to deliver results in early 2021. A larger Phase 3 trial in the United States is expected to launch by the end of December..
Transport	In September Novavax reached an agreement with the Serum Institute of India, a major vaccine manufacturer, that they said would enable them to produce as many as 2 billion doses a year. If the trials succeed, Novavax expects to deliver 100 million doses for use in the United States by the first quarter of 2021. On Nov. 4 they announced another agreement to deliver 40 million doses to Australia.

Candidate	Mechanism	Trial Phase	Institution
Ad5-nCoV	Recombinant vaccine (adenovirus type 5 vector)	Phase 3	Tongji Hospital

The Chinese company **CanSino Biologics** developed a vaccine based on an adenovirus called Ad5, in partnership with the Institute of Biology at the country's **Academy of Military Medical Sciences**. In May, they published promising results from a Phase 1 safety trial, and in July they reported that their Phase 2 trials demonstrated the vaccine produced a strong immune response. In an unprecedented move, the Chinese military approved the vaccine on June 25 for a year as a "specially needed drug." CanSino would not say whether vaccination would be mandatory or optional for soldiers. Starting in August, CanSino began running Phase 3 trials in a number of countries, including Saudi Arabia, Pakistan and Russia.

Study Design/Trials	Multiple trials are in various stages of recruitment and completion: - A Phase 1 clinical trial in China of 108 participants between 18 and 60 years old who will receive low, medium, and high doses of Ad5-nCoV is active, but not recruiting (NCT04313127). - A Phase 1 trial in China is evaluating intramuscular vaccination and mucosal vaccination of Ad5-nCoV across two doses (NCT04552366). - A Phase 1/2 trial of up to 696 participants in Canada (NCT04398147). - A Phase 2 double-blind, placebo-controlled trial of up to 508 participants in China (NCT04341389) is active, but not recruiting. - A Phase 2b trial in China evaluating safety and immunogenicity of Ad5-nCoV in participants 6 years and older (NCT04566770). - A Phase 3 trial in Russia of up to 500 participants across multiple study centers (NCT04540419). - A Phase 3 trial of up to 40,000 participants internationally, including Pakistan, Saudi Arabia and Mexico (NCT04526990).
Outcomes	A single dose of Ad5-nCoV protected against upper respiratory infection of SARS-CoV-2 in ferrets, according to a paper published 14 August in *Nature Communications*. Results from a Phase 1 trial show a humoral and immunogenic response to the vaccine, according to a paper published in *The Lancet*. Adverse reactions such as pain (54%), fever (46%), fatigue (44%), headache (39%), and muscle pain (17%) occurred in 83% of patients in the low and medium dose groups and 75% of patients in the high dose group. In the Phase 2 trial, neutralizing antibodies and specific interferon γ enzyme-linked immunospot assay responses were observed at all dose levels for most participants.
Status	On 25 June, China's Central Military Commission announced the military had been approved to use Ad5-nCoV for a period of 1 year, according to reporting in Reuters.

Candidate	Mechanism	Trial Phase	Institution
CoronaVac	Inactivated vaccine (formalin with alum adjuvant)	Phase 3	Sinovac Research and Development Co., Ltd.

Chinese company Sinovac's CoronaVac uses an inactivated virus -- one of the oldest methods for vaccinating people. Whole batches of coronavirus are grown, "killed" and then made into vaccine. The vaccine is called CoronaVac. CoronaVac (formerly PiCoVacc) is a formalin-inactivated and alum-adjuvanted candidate vaccine. Results from animal studies showed "partial or complete protection in macaques" exposed to SARS-CoV-2, according to a paper published in *Science*.

Study Design/Trials	A Phase 1/2 trial of 743 healthy volunteers (18-59 years old) who received two different dosages of the vaccine or placebo is active but not recruiting. A Phase 1 trial of 143 participants (NCT04352608) and a Phase 2 trial of 600 participants (NCT04383574) are both active but not recruiting. Sinovac said a Phase 3 trial in collaboration with Instituto Butantan in Brazil is underway (NCT04456595), and the company plans to enroll around 9,000 patients in the healthcare industry. Trials also are underway in Turkey (NCT04582344) and in Indonesia (NCT04508075).In June the company announced that Phase 1/2 trials on 743 volunteers found no severe adverse effects and produced an immune response. Sinovac published the details of the trial in November in a medical journal, showing a comparatively modest production of antibodies. Only a Phase 3 trial would demonstrate if that was enough to protect people from Covid-19. In July, Sinovac launched a Phase 3 trial in Brazil, followed by others in Indonesia and Turkey. While Sinovac has yet to release late-stage trial data, on Oct. 19 officials in Brazil said that it was the safest of five vaccines they were testing in Phase 3 trials.
Outcomes	Results from the Phase 1/2 trials published in *The Lancet Infectious Diseases* indicate the vaccine has good safety and immunogenicity, with seroconversion occurring in 92.4% of participants receiving the 3 µg dose on a 0-14 day schedule and 97.4% of individuals receiving the same dose on a 0-28 day schedule.
Status	Representatives from Sinovac told Reuters that the vaccine appeared to be safe in older trial participants, and did not cause any severe side effects. Preliminary results from the Instituto Butantan trial announced by the company indicate CoronaVac is safe so far, with no serious adverse events reported. Reuters reported that the Chinese government gave the Sinovac vaccine an emergency approval for limited use in July. In October, authorities in the eastern Chinese city of Jiaxing announced they were giving CoronVac to people in relatively high-risk jobs, including medical workers, port inspectors and public service personnel. On Nov. 9, the Brazilian government announced they had paused the country's Sinovac trial the previous month because of an adverse event. (patient death). Two days after the announcement, the trial was allowed to resume. Meanwhile, Sinovac has been preparing to manufacture the vaccine for global distribution, reaching an agreement to supply Indonesia with at least 40 million doses by March 2021. In September, Yin Weidong, the CEO of Sinovac, said the company planned on worldwide distribution of the vaccine in early 2021 — including the United States.

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ

Gamaleya Research Institute, Acellena Contract Drug Research and Development

Candidate	Mechanism	Trial Phase	Institution
Sputnik V	Non-replicating viral vector	Phase 3	Various

The **Gamaleya Research Institute**, part of Russia's Ministry of Health, has created a vaccine based on two adenoviruses. Preliminary results announced in November indicate that the vaccine has a high efficacy rate in Phase 3 trials. Gamaleya produced the vaccine, initially called Gam-Covid-Vac, from adenoviruses called Ad5 and Ad26. Both kinds have been tested as vaccines over the years. By combining them, the Russian researchers hoped to avoid a situation in which the immune system could learn to recognize the vaccine as a foreign object that needed to be destroyed.

Study Design/Trials	Phase 1/2 trials recruited about 38 participants each to receive the vaccine candidate (NCT04436471) (NCT04437875) and are completed. Sputnik V is additionally being evaluated in a small Phase 2 trial of 110 participants older than 60 years (NCT04587219). A Phase 3 trial of about 40,000 participants at multiple centers in Russia is underway (NCT04530396). Outside Russia, Sputnik V is being tested in Belarus (NCT04564716) and the United Arab Emirates The researchers launched clinical trials in June. On Aug. 11, President Vladimir V. Putin announced that a Russian health care regulator had approved the vaccine, renamed Sputnik V, before Phase 3 trials had even begun. Vaccine experts decried the move as risky, and Russia later walked back the announcement, saying that the approval was a "conditional registration certificate," which would depend on positive results from Phase 3 trials. Those trials, initially planned for just 2,000 volunteers, were expanded to 40,000. In addition to Russia, volunteers were recruited in Belarus, the United Arab Emirates, and Venezuela. On Oct. 17, a Phase 2/3 trial was launched in India.
Outcomes	Results from the two small Phase 1/2 trials published in *The Lancet* appear to show the vaccine has a good safety profile and "induced strong humoral and cellular immune response" in participants. The Russian Direct Investment Fund announced the vaccine was 92% effective in interim trial results based on 20 participants. On Nov. 11, the Russian Direct Investment Fund announced preliminary evidence from their Phase 3 trial indicating that the vaccine is effective. Based on 20 cases of Covid-19 among the trial participants, Russian scientists estimated that the vaccine demonstrated 92 percent efficacy. On Nov. 24, the vaccine makers followed up with an analysis on 39 cases that pointed to the same efficacy rate. They also claimed that a preliminary analysis on some volunteers who had the vaccine for a longer period of time showed a 95 percent efficacy rate, but outside experts questioned that conclusion.
Status	The Health Ministry of the Russian Federation has approved Sputnik V as the first vaccine for COVID-19. However, no trial data has been published to date. The approval has drawn criticism in the medical community due to lack of data on safety and efficacy.
Transport	Russia's Sputnik V coronavirus vaccine is an adenoviral vector vaccine. It uses two common cold viruses called adenovirus 5 and adenovirus 26 to carry the genetic material for the spike protein into the body.

Candidate	Mechanism	Trial Phase	Institution
No name announced	Inactivated vaccine	Phase 3	Henan Provincial Center for Disease Control and Prevention

The state-owned Chinese company **Sinopharm** is currently testing two vaccines based on inactivated coronaviruses. One of them was created by the **Wuhan Institute of Biological Products.** The Phase 1/2 trial showed that the vaccine produced antibodies in volunteers, some of whom experienced fevers and other side effects.

Study Design/Trials	Researchers at Sinopharm and the Wuhan Institute of Virology under the Chinese Academy of Sciences are developing an inactivated COVID-19 vaccine candidate. They have initiated a randomized, double-blind, placebo parallel-controlled Phase 1/2 clinical trial (ChiCTR2000031809) of healthy individuals starting at 6 years old.
Outcomes	The vaccine has shown a "strong neutralizing antibody response" in Phase 1/2 trials, according to a release from China National Biotec Group. Results from a Phase 1 and a Phase 2 trial published in *JAMA* show the vaccine candidate has demonstrated immunogenicity.
Status	On Sept. 14, the U.A.E. gave emergency approval for Sinopharm's vaccine to use on health care workers, and soon government officials and others were also receiving it. In China, Sinopharm has been even more aggressive in distributing its vaccines. Over the summer, the company later said, the Chinese government gave it approval to inject both vaccine candidates into government officials, health care workers, and other select groups. By November, the chairman of Sinopharm said, almost a million people in China had received the vaccines. On Nov. 25, Sinopharm announced it had filed an application to market its vaccines in China--despite the fact that it has not yet finished its Phase 3 trials that would e demonstrate that they are safe and effective. A Phase 3 trial is underway in Peru, Morocco, and in the United Arab Emirates.

Candidate	Mechanism	Trial Phase	Institution
Covaxin	Inactivated vaccine	Phase 3	

In collaboration with the **Indian Council of Medical Research** and the **National Institute of Virology**, the Indian company **Bharat Biotech** designed a vaccine called Covaxin based on an inactivated form of the coronavirus. Studies on monkeys and hamsters found that it provided protection against infection. In June, Bharat's coronavirus vaccine became the first created in India to go into clinical trials. While the results of the Phase 1/2 trials have yet to be published, an executive at Bharat told India Today that about 85 to 90 percent of the 1,000 volunteers produced antibodies to the coronavirus and experienced no serious adverse effects due to Covaxin.

Study Design/Trials	A Phase 1/2 trial of about 1,100 healthy participants is underway after approval by the Drug Controller General of India. The Indian Council of Medical Research (ICMR) has reported Covaxin has entered Phase 2 trials. The Director General of ICMR said a Phase 3 trial of 26,000 participants is underway.
Outcomes	Results of a two-dose regimen given to rhesus macaques posted to the pre-print server *Research Square* showed an increase in SARS-CoV-2 specific IgG and neutralizing antibodies and reduced viral replication in the nasal cavity, the throat, and the lung. Early results in the first 50 people who received the vaccine candidate appear to be "encouraging," according to the trial's principal investigator. The first two phases of the trial did not have any major adverse events, Bharat Biotech said in a statement.
Status	On Oct. 23, the company announced they were initiating a Phase 3 trial. Bharat expects results in early 2021 and could begin distribution "as early as February 2021," according to an ICMR scientist who spoke with Reuters.

Candidate	Mechanism	Trial Phase	Institution
VIR-7831	Plant-based adjuvant vaccine	Phase 2/3	Medicago

Canada-based **Medicago** grows vaccines in a plant called Nicotiana benthamiana, a wild species related to tobacco. They deliver virus genes into leaves, and the plant cells then create protein shells that mimic viruses. In July, Medicago launched Phase 1 trials on a plant-based Covid-19 vaccine in combination with adjuvants to boost the immune system's response to the viral proteins. In that study, they found that an adjuvant made by GSK produced promising levels of antibodies in volunteers. On Oct. 23, the company announced it had reached an agreement with the government of Canada to supply 76 million doses.

Study Design/Trials	A Phase 1 trial of up to 180 participants 18-55 years old who will receive the vaccine in doses of 3.75 µg, 7.5 µg, and 15 µg (NCT04450004) is active, but not recruiting. The Phase 2 portion of the Phase 2/3 COMET-ICE trial, evaluating safety, tolerability, efficacy, and pharmacokinetics of the vaccine in up to 1,360 participants, is underway (NCT04545060).
Outcomes	A single dose of Medicago's vaccine candidate in mice yielded a positive antibody response after 10 days, according to a company release. Results from the Phase 1 trial posted to the pre-print server *medRxiv* show the vaccine was tolerated safely and generated an immune response in all participants after two doses. A Phase 2/3 trial of the vaccine began on Nov. 12.
Status	Medicago and GSK said they hope to move forward with the Phase 3 portion of the COMET-ICE trial by the end of the year.

About Us

McDougall Scientific is a Clinical Research Organization with over 35 years of experience specializing in Clinical Statistical Analysis services, Trial Design, top-tier data management & reporting.

A highly reputed firm in multiple therapeutic areas and indications supporting clinical trials from Phase I to Phase IV. The high repeat and referral client rate is the best testimony to their proven, nimble approach.

www.mcdougallscientific.com

With over 20 years of consistent and successful results, SPharm has become one of the leading Drug Regulatory Advisory firms in Canada.

Drug companies from around the world count on SPharm to help them navigate the drug (and other health products) review & approval process.

www.spharm-inc.com