2021 COVID-19 VACCINES

Summary, updates & status

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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:

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/

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

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

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

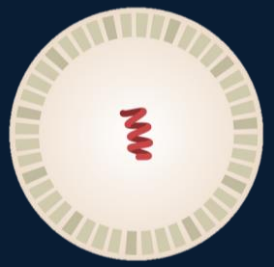
https://www.cnn.com/2020/11/24/health/covid-vaccines-design-explained/index.html

Health Canada 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.

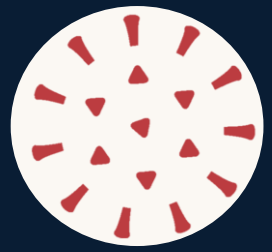


GENETIC VACCINES

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.

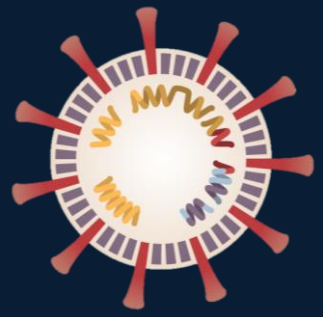
VIRAL VECTOR VACCINES

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.

Approved or Approved for Emergency Use Vaccines

Approved Covid-19 Vaccines

	Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
Pfizer BIONTECH	Comirnaty (BNT162b2)	mRNA-based vaccine	Pfizer, BioNTech; Fosun Pharma	95%	2 doses, 3 weeks apart TYPE: Muscle injection	Freezer storage only at –94°F (–70°C)	Multinational
moderna	Moderna COVID-19 Vaccine (mRNA-1273)	mRNA-based vaccine	Moderna, BARDA, NIAID	94.5%	2 doses, 4 weeks apart TYPE: Muscle injection	30 days with refrigeration, 6 months at –4°F (–20°C)	US
AstraZeneca	COVID-19 Vaccine AstraZeneca (AZD1222); also known as Covishield	Adenovirus vaccine	BARDA, OWS	62% to 90%, depending on dosage	2 doses, 4 weeks apart TYPE: Muscle injection	Stable in refrigerator for at least 6 months	UK
CanSinoBIO	Convidecia (also known as Ad5-nCoV)	Recombinant vaccine (adenovirus type 5 vector)	CanSino Biologics	Unknown	Single dose TYPE: Muscle injection	Refrigerated	China
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ	Sputnik V (also known as Gam-Covid-Vac)	Non-replicating viral vector	Gamaleya Research Institute, Acellena Contract Drug Research and Development	91.4%	2 doses, 3 weeks apart TYPE: Muscle injection	Freezer storage. Developing an alternative formulation that can be refrigerated.	Russia
BHARAT BIOTECH	Covaxin (also known as BBV152 A, B, C)	Inactivated vaccine	Bharat Biotech, ICMR	Unknown	2 doses, 4 weeks apart	At least a week at room temperature	India
sinovac	CoronaVac (formerly PiCoVacc)	Inactivated vaccine	Sinovac Research and Development Co., Ltd.	50.38%	2 doses, 2 weeks apart TYPE: Muscle injection	Refrigerated	China
SINOPHARM	BBIBP-CorV	Inactivated vaccine	Beijing Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	79.34%	2 doses, 3 weeks apart TYPE: Muscle injection	?	China
BEKTOP	EpiVacCorona	Peptide vaccine	Federal Budgetary Research Institution State Research Center of Virology and Biotechnology	Unknown	2 doses, 3 weeks apart TYPE: Muscle injection	Stable in refrigerator for up to two years	Russia

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
Comirnaty (BNT162b2)	mRNA-based vaccine	Pfizer, BioNTech; Fosun Pharma	95%	2 doses, 3 weeks apart TYPE: Muscle injection	Freezer storage only at –94°F (–70°C)	Multinational

Background	Comirnaty (formerly BNT162b2) is a nucleoside modified mRNA-based vaccine developed by BioNTech and Pfizer. Fosun Pharma has licensed Comirnaty in China. The vaccine is given as an intramuscular injection in two doses 21 days apart; however, some countries are changing that dosing schedule. Comirnaty generates an immune response against SARS-CoV-2, the virus that causes COVID-19, by encoding a mutated form of the full spike protein of the virus.
Study Design/Trials	A pivotal Phase 2/3 trial of more than 43,000 healthy participants around the world (NCT04368728) published in NEJM, a Phase 2 trial of 960 participants in China in conjunction with Shanghai Fosun Pharmaceutical (NCT04649021), a Phase 1/2 trial in the US and Germany of 200 healthy participants between aged 18-55 years (NCT04380701), and a combined Phase 1/2 trial of 160 participants (NCT04588480) in Japan. Phase 3 data of 43,448 participants published in NEJM showed Comirnaty was 95% effective. Those results are backed up by Phase 1 data published in NEJM showing similar immunogenicity between Comirnaty and another BNT162 variant developed by Pfizer and BioNTech, but fewer adverse effects were seen with Comirnaty. Results from a pre-print posted to *bioRxiv* also indicate the Pfizer vaccine is effective against the B.1.1.7 variant of SARS-CoV-2 first identified in the UK. On 29 January, EMA released its first safety update on Comirnaty, indicating that "safety data collected on Comirnaty use in vaccination campaigns is consistent with the known safety profile of the vaccine, and no new side effects were identified." Further, EMA's safety committee found no link between pos-vaccination deaths and the vaccine, even in elderly and frail people.
Regulatory Actions	**APPROVED FOR USE IN:** Bahrain, Saudi Arabia, Switzerland. **EMERGENCY USE IN:** Argentina, Australia, Canada, Chile, Colombia, Costa Rica, Ecuador, European Union, Iraq, Jordan, Kuwait, Lebanon, Malaysia, Mexico, Oman, Panama, Qatar, Serbia, Singapore, Switzerland, Tunisia, United Arab Emirates, United Kingdom, United States. Emergency use validation from the World Health Organization.

moderna

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
Moderna COVID-19 Vaccine (mRNA-1273)	mRNA-based vaccine	Moderna, BARDA, NIAID	94.5%	2 doses, 4 weeks apart TYPE: Muscle injection	30 days with refrigeration, 6 months at –4°F (–20°C)	US

Background	Moderna COVID-19 Vaccine (formerly known as mRNA-1273) was developed by Moderna based on prior studies of related coronaviruses. It is a two-dose mRNA vaccine taken 28 days apart. The WHO Strategic Advisory Group of Experts (SAGE) on Immunization has issued guidance for use of the vaccine in adults.
Study Design/Trials	In the pivotal Phase 3 trial of 30,000 participants at high risk for COVID-19, participants received a 100 µg dose of the Moderna COVID-19 Vaccine and another 4 weeks later or placebo injections and then be followed for up to 2 years; results published in *NEJM* demonstrated efficacy of 94.1% (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). Moderna has also launched a Phase 2/3 trial testing Moderna COVID-19 Vaccine in about 3,000 adolescents 12 years to less than 18 years old (NCT04649151).
Regulatory Actions	- US: EUA issued 18 December, - Canada: Authorized 23 December. - Israel: authorized on 4 January. - EU: authorization from EMA for the vaccine 6 January. - Faroe Islands: Approved for use on 6 January. - Greenland: Approved for use on 6 January. - Iceland: Approved for use on 6 January. - Norway: Approved for use on 6 January. - UK: MRHA granted on 8 January. - France: authorized on 8 January. - Switzerland: authorized the vaccine 12 January. - Saudi Arabia: On 18 January, Saudi Arabia approved the vaccine.

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
COVID-19 Vaccine AstraZeneca (AZD1222); also known as Covishield	Adenovirus vaccine	BARDA, OWS	62% to 90%, depending on dosage	2 doses, 4 weeks apart TYPE: Muscle injection	Stable in refrigerator for at least 6 months	UK

Background	AstraZeneca and the Oxford Vaccine Group at the University of Oxford have developed "COVID-19 Vaccine AstraZeneca" (previously AZD1222 and ChAdOx1), a chimpanzee adenovirus vaccine. In India, the candidate is being jointly developed by the Serum Institute of India and AstraZeneca, and goes by the name Covishield. Two vaccine is administered in two doses between 4-12 weeks apart.
Study Design/Trials	A Phase 3 trial (NCT04516746), for which AstraZeneca released the clinical study protocol, is underway and has enrolled more than 40,000 participants. A Phase 2/3 trial (COV002) conducted by the University of Oxford of up to 12,390 participants, is active and currently recruiting (NCT04400838). A Phase 1/2 (NCT04324606) single-blinded, multi-center study (COV001) of 1,090 healthy adult volunteers aged 18-55 years with four treatment arms, and a Phase 1/2 trial of healthy participants in South Africa (NCT04444674) are both active but not recruiting. An inhaled version of the vaccine candidate is being tested in a small trial of 30 people. Interim data from a Phase 3 trial in the UK, Brazil, and South Africa published in *The Lancet* indicate the vaccine has an overall efficacy of 70%, with vaccine efficacy at 62.1% in a group of participants receiving two standard doses and 90% in a group receiving one half dose followed by a standard dose. A report of Phase 2 data from the Phase 2/3 COV002 trial published in *The Lancet* showed the vaccine candidate has similar immunogenicity in patients of all ages but appears to be better tolerated in older adults. Preliminary results from the 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.
Regulatory Outcomes	- UK: On 29 December, authorized COVID-19, - Argentina: Authorized on 30 December. - El Salvador: Authorized on 30 December. - Dominican Republic: Authorized for emergency use on 31 December. - India: Authorized for emergency use on 3 January. - Bangladesh: Authorized for emergency use on 4 January. - Mexico: Authorized for emergency use by Cofepris on 4 January. - Nepal: Authorized for emergency use on 15 January. - Pakistan: Authorized for emergency use on 16 January. - Brazil: Authorized for emergency use on 17 January by Anvisa. - Saudi Arabia: Authorized for emergency use on 18 January. - Iraq: Authorized for emergency use on 19 January. - Hungary: Authorized for emergency use 20 January. - Thailand: EUA granted 21 January. - Sri Lanka: Authorized for emergency use on 22 January. - Ecuador: Authorized for emergency use on 24 January. - Bahrain: Authorized for emergency use on 25 January. - South Africa: Authorized for emergency use by SAHPRA on 27 January. - Chile: Authorized for emergency use by ISP on 27 January. - Myanmar: A vaccine rollout began in the country on 27 January. - EU: Granted conditional marketing authorization by the EMA on 29 January. – Canada: Health Canada also has undertaken a rolling review. In Australia, TGA granted AstraZeneca's vaccine provisional determination, the first step in the process for approval.

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
Convidecia (also known as Ad5-nCoV)	Recombinant vaccine (adenovirus type 5 vector)	BARDA, OWS	Unknown	Single dose TYPE: Muscle injection	Refrigerated	China

Background	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 Convidicea is active, but not recruiting (NCT04313127). - A Phase 1 trial in China is evaluating intramuscular vaccination and mucosal vaccination of Convidicea 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 Convidicea 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 Convidicea for a period of 1 year, according to reporting in Reuters. A vaccine developed by CanSino has been submitted to the Mexican health regulator Cofepris for review, but it has not been clarified whether this vaccine is Convidicea. Starting in August 2020, CanSino began running Phase 3 trials in a number of countries, including Pakistan, Russia, Mexico and Chile. In February, Reuters reported that an interim look at the trial did not reveal any safety concerns, allowing the study to continue.

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ

Gamaleya Research Institute,
Acellena Contract Drug Research and Development

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
Sputnik V (also known as Gam-Covid-Vac)	Non-replicating viral vector	Gamaleya Research Institute, Acellena Contract Drug Research and Development	91.4%	2 doses, 3 weeks apart TYPE: Muscle injection	Freezer storage. Developing an alternative formulation that can be refrigerated.	Russia

Background	The Gamaleya Research Institute in Russia and Health Ministry of the Russian Federation are evaluating their non-replicating viral vector vaccine, Sputnik V (formerly Gam-COVID-Vac), in a Phase 3 trial in Russia and internationally.
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.
Regulatory Outcomes	- Russia: approved Sputnik V as the first vaccine for COVID-19. However, Phase 3 data on this vaccine have yet to be published. The approval has drawn criticism in the medical community due to lack of data on safety and efficacy. - Belarus: Registered for use in the country on 21 December. - Argentina: Registered on 23 December. - Guinea: receiving the vaccine on an experimental basis as of 31 December. - Bolivia: Registered for use on 6 January. - Serbia: Authorized 6 January. - Algeria: for emergency use on 10 January. - Palestine: On 11 January, approved Sputnik V. - Venezuela: Authorized for emergency use on 13 January. - Paraguay: Authorized for emergency use on 15 January. - Turkmenistan: Registered for emergency use on 18 January. - Hungary: Provisional medicinal product authorization granted 21 January. - UAE: Authorized for emergency use on 21 January. - Hungary: Approved on 21 January. - Iran: Approved for use in the country on 26 January. - Mexico: vaccine rollout has begun despite Mexico not yet approving Sputnik V. The Gamaleya Research Institute has filed for vaccine registration of Sputnik V in the EU. They have also made a preliminary presubmission of the vaccine in Brazil, which is required for its use in the country. The institute has applied for emergency use authorization of the vaccine in the Philippines. The vaccine is also being considered in Mexico. Pakistan's regulatory authority has accepted the Sputnik V data and the vaccine is close to approval in the country.

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
Covaxin (also known as BBV152 A, B, C)	Inactivated vaccine	Bharat Biotech, ICMR	Unknown	2 doses, 4 weeks apart	At least a week at room temperature	India

Background	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 began in July of 2020 after approval by the Drug Controller General of India. ICMR reported Covaxin entered Phase 2 trials in August. A Phase 3 trial of 26,000 participants is underway, according to the Director General of ICMR, which has reached about half of its enrollment target. Bharat Biotech is also planning a clinical trial in Bangladesh.
Regulatory Outcomes	On 16 December, Bharat Biotech reported that Covaxin was "safe and triggered immune responses" in a Phase 1 trial. The first two phases of the trial did not have any major adverse events, the company said in a statement. Early results in the first 50 people who received the vaccine candidate appear to be "encouraging," according to the trial's principal investigator. On Jan. 3, the Indian government granted Covaxin emergency authorization. The authorization came despite no release of Phase 3 data showing the vaccine is safe and effective. On Jan. 26, Bharat researchers reported that antibodies from the Covaxin vaccine can block B.1.1.7, the variant first identified in the United Kingdom in December.

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
CoronaVac (formerly PiCoVacc)	Inactivated vaccine	Sinovac Research and Development Co., Ltd.	50.38%	2 doses, 2 weeks apart TYPE: Muscle injection	Refrigerated	China

Background	CoronaVac (formerly PiCoVacc) is a formalin-inactivated and alum-adjuvanted vaccine developed by the China-based biotechnology company Sinovac Biotech. The vaccine is administered in two doses 14-28 days apart.
Study Design/Trials	Several large international trials including Phase 3 trials with the Instituto Butantan in Brazil (NCT04456595), Turkey (NCT04582344) and in Indonesia (NCT04508075), and a trial of up to 9,000 patients in the healthcare industry. Previously, Sinovac launched a Phase 1/2 trial of 743 healthy volunteers and a Phase 1 trial of 143 participants (NCT04352608) and a Phase 2 trial of 600 participants (NCT04383574). There has been some variations in the vaccine's efficacy across clinical trials. Preliminary results from the Instituto Butantan trial announced by the company indicate CoronaVac is safe so far, with no serious adverse events reported. Effectiveness of the vaccine has varied by region. In Phase 3 trials, efficacy is above 50%, according to independent reporting from the *Wall Street Journal*. Estimates of efficacy from trials in Brazil were originally at 78%, but were revised to 50.4% after including patients with mild infections. Another announcement made on 18 January indicates spreading out the dosing interval may increase the effectiveness of the vaccine by as much as 20 percentage points. According to officials in Turkey, the effectiveness of the vaccine is 91.25%. Representatives from Sinovac told Reuters that the vaccine appeared to be safe in older trial participants, and did not cause any severe side effects. The trial in Brazil was briefly suspended due to a patient death, but resumed. 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.
Regulatory Outcomes	- China: China has approved CoronaVac as part of an emergency use program in the country for "high-risk" individuals such as health care workers and essential personnel. - Bolivia: Authorized the vaccine for emergency use on 6 January. - Indonesia: Authorized for emergency use by the Indonesian food and drug monitoring agency (BPOM) on 12 January. - Turkey: Granted emergency use authorization on 14 January. - Brazil: Authorized for emergency use on 17 January by Anvisa. - Chile: Authorized for emergency use on 20 January.

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
BBIBP-CorV	Inactivated vaccine	Beijing Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	79.34%	2 doses, 3 weeks apart TYPE: Muscle injection	?	China

Background	The state-owned Chinese company **Sinopharm** is currently testing two vaccines based on inactivated coronaviruses. Sinopharm is developing a second inactivated COVID-19 vaccine candidate, BBIBP-CorV, with the Beijing Institute of Biological Products.
Study Design/Trials	Sinopharm has initiated a randomized, double-blind, placebo parallel-controlled Phase 1/2 clinical trial (ChiCTR2000031809) of healthy individuals starting at 6 years old, and a Phase 3 trial is underway in Peru, Morocco, and in the United Arab Emirates. 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.
Regulatory Outcomes	- China: On 30 December, China conditionally approved BBIBP-CorV based on interim Phase 3 clinical trial results showing 79% efficacy. Late stage trial data have not yet been published for this vaccine. - United Arab Emirates: granted limited emergency use. - Bahrain: approved the registration of BBIBP-CorV. - Egypt: approved the Sinopharm vaccine for use in the country. - Jordan: On 10 January authorized for emergency use. - Pakistan: Authorized for emergency use on 18 January. - Iraq: Approved on 20 January. - Serbia: begun a vaccine rollout as of 20 January despite the lack of approval or authorization of BBIBP-CorV in the EU. - Peru: "Exceptional approval" has been granted

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
EpiVacCorona	Peptide vaccine	Federal Budgetary Research Institution State Research Center of Virology and Biotechnology	Unknown	2 doses, 3 weeks apart TYPE: Muscle injection	Stable in refrigerator for up to two years	Russia

Background	The Federal Budgetary Research Institution State Research Center of Virology and Biotechnology in Russia (the Vector Institute) has developmed a peptide vaccine for COVID-19 called EpiVacCorona.
Study Design/Trials	A Phase 1/2 trial in Russia is active, but not recruiting, which is evaluating the effectiveness of the vaccine in up to 100 participants (NCT04527575). On 30 September, clinical trials of the vaccine had been completed after beginning in July, according to reporting from Reuters. Post-registration trials for EpiVacCorona have reportedly begun in Russia, according to the Russian Federal Service for the Oversight of Consumer Protection. The head of the zoonotic diseases and flu department with the Russian State Research Center of Virology and Biotechnology Vector has said participants have developed immunity "a month after the first vaccination," but no official trial data has yet been released.
Regulatory Outcomes	In January, Russia launched a mass vaccination campaign, using EpiVacCorona as well as Sputnik V, an adenovirus-based vaccine. The Vector Institute has yet to announce the details of its Phase trial indicating whether the vaccine is effective or not.

Potential Vaccine Candidates

NOVAVAX
Creating Tomorrow's Vaccines Today

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
NVX-CoV2373	Nanoparticle vaccine	Novavax	89.3% against most variants	2 doses, 3 weeks apart TYPE: Muscle injection	Stable in refrigerator	US

Background	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.
Study Design/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). A Phase 3 trial of more than 15,000 participants aged 18-84 years is underway in the UK (NCT04583995). The Phase 3 PREVENT-19 trial has been launched in the United States and Mexico (NCT04611802).
Outcomes	Novavax has received Fast Track Designation from the FDA for NVX-CoV2373. 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. Novavax provided an update on 27 October of its Phase 3 trial of NVX-CoV2373 in North America. In September, Novavax reached an agreement with the Serum Institute of India, a major vaccine manufacturer, that could enable them to produce as many as 2 billion doses a year. If its clinical trials succeed, Novavax expects to deliver 100 million doses for use in the United States in 2021. They also have an agreement with other countries, including one to the United Kingdom for 60 million doses, with Canada for 52 million doses, and with Australia for 51 million doses.

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
JNJ-78436735 (formerly Ad26.COV2.S)	Non-replicating viral vector	Johnson & Johnson	72% in United States, 66% in Latin America, 57% in South Africa	1 dose TYPE: Muscle injection	Up to two years frozen at –4° F (–20° C), and up to three months refrigerated at 36–46° F (2–8° C).	US

Background	Janssen, a pharmaceutical company owned by 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. In partnership with BARDA, Janssen has committed to investing more than $1 billion in vaccine research and development. JNJ-78436735 is a part of Operation Warp Speed.
Study Design/Trials	The Phase 3 ENSEMBLE trial will enroll up to 60,000 participants in the United States and internationally (NCT04505722). On 23 September, Janssen 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). Additionally, a randomized, double-blind, placebo-controlled, Phase 1/2a study of JNJ-78436735 is ongoing 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).
Status	The ENSEMBLE trial was temporarily on hold pending a review of an adverse event a participant developed in one of the study arms, but resumed in the US and Brazil after Independent Data Safety and Monitoring Board review. Janssen 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. On Nov. 16, Johnson & Johnson announced that they were also launching a second Phase 3 trial to observe the effects of two doses of their vaccine, instead of just one. The results are expected in early spring.

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
VIR-7831	Plant-based adjuvant vaccine	Medicago; GSK; Dynavax	?	2 doses, 3 weeks apart TYPE: Muscle injection	Stable in refrigerator	Canada

Background	Medicago, which recently developed a seasonal recombinant quadrivalent virus-like particle (VLP) influenza vaccine, reported they created a coronavirus VLP vaccine 20 days after working with the SARS-CoV-2s genome. Medicago is also testing the candidate with two additional vaccine adjuvants from GSK and Dynavax
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).
Status	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. A Phase 2/3 trial of the vaccine began on Nov. 12.

Name	Vaccine Type	Primary Developers	Efficacy	Dose	Storage	Country of Origin
CVnCoV	mRNA-based vaccine	CureVac	?	2 doses, four weeks apart TYPE: Muscle injection	Stable at least 3 months at 36–46°F (2–8°C)	Germany

Background	CureVac is developing an mRNA-based vaccine, CVnCoV. The vaccine works by using non-chemically modified nucleotides within mRNA to "provide a strong and balanced activation of the immune system." Pre-clinical results have shown virus neutralizing titers and T-cell response to the candidate and balanced humoral and cellular immune responses in mice and hamsters.
Study Design/Trials	CureVac is evaluating CVnCoV in a Phase 1 trial of 168 healthy subjects in Germany and Belgium (NCT04449276). A Phase 2 dose-confirmation trial with up to 691 participants currently recruiting (NCT04515147). A mid-stage Phase 2a study in Peru and Panama is also underway. In Germany, CureVac has launched the Phase 2b/3 HERALD trial of more than 36,000 participants (NCT04652102). A complementary Phase 3 trial at the University Medical Center Mainz of more than 2,500 healthcare workers is also underway (NCT04674189). A Phase 3 trial in Mexico has also begun, according to Reuters.
Outcomes	In December, CureVac launched a Phase 3 trial, recruiting up to 36,500 volunteers in Germany. In November, CureVac negotiated a deal to provide the European Union with up to 225 million doses of their vaccine. They project manufacturing up to 300 million doses in 2021 and up to 600 million doses the following year. On Jan. 8, CureVac announced that it had formed a partnership with pharmaceutical giant Bayer, which would support the vaccine's development and production.

The Authors of this Report

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