VACCINE INFO

Coronavirus Vaccines

Coronaviruses without preventive vaccines are the Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV), and the novel coronavirus (/condition/coronavirus) SARS-CoV-2, which causes COVID-19 disease in humans.

As of May 14, 2020, the U.S. FDA has not approved any preventive or therapeutic vaccines for use against the SARS, MERS, or SARS-CoV-2 coronaviruses. However, over 300 clinical studies are seeking participants to evaluate vaccine candidates.

SARS-CoV-2 Coronavirus Vaccine Candidates: Human Clinical Trials

The SARS-CoV-2 vaccine development landscape includes innovative platforms such as nucleic acid (DNA and RNA), virus-like particle, peptide, viral vector (replicating and non-replicating), recombinant protein, live attenuated virus and inactivated virus approaches.

Phase 4 Clinical Trial

- BCG (/vaccines/bacille-calmette-guerin-tuberculosis-vaccine) - Bacille Calmette-Guerin is an attenuated, live culture preparation of the Bacillus of Calmette and Guerin (BCG) strain of Mycobacterium bovis.

    - April 28, 2020 - Texas universities announced they are asking 1,800 frontline medical workers to participate in a phase 4 clinical trial (/texas-am-baylor-md-anderson-covid-19-prevention-study-uses-approved-tuberculosis-vaccine) of an old tuberculosis vaccine, BCG, to determine its ability to protect people from the SARS-CoV-2 coronavirus. This study includes the Harvard's School of Public Health, Cedars Sinai Medical Center in Los Angeles, the University of Texas MD Anderson Cancer Center in Houston, and the Baylor College of Medicine in Houston, Texas.

Phase 3 Clinical Trials

- BCG (/vaccines/bacille-calmette-guerin-tuberculosis-vaccine) - Bacille Calmette-Guerin (BCG)
    - April 7, 2020: A phase 3 study is an Open-label, two-group, randomized controlled trial in up to 4,170 Australian healthcare workers to determine if BCG vaccination reduces the incidence and severity of COVID-19 disease during the 2020 pandemic.
    - April 3, 2020: A phase 3 study in the Netherlands reducing Health Care Workers Absenteeism in COVID-19 Pandemic Through BCG Vaccine (BCG-CORONA)
- VPM1002 (/vaccines/vpm1002-tuberculosis-vaccine) - A Phase 3 study is investigating whether the BCG vaccine candidate VPM1002, originally developed against tuberculosis by scientists at the Max Planck Institute for Infection Biology, is also effective against infection with SARS-CoV-2. The large-scale study is to be carried out at several hospitals in Germany and will include older people and health care, workers.

Phase 2 Clinical Trials

- mRNA-1273 SARS-CoV-2 Vaccine (/vaccines/mrna-1273-sars-cov-2-vaccine) - May 7, 2020 - Stéphane Bancel, Moderna's CEC, said, "The imminent Phase 2 study start is a crucial step forward as we continue to advance the clinical development of mRNA-1273. With the goal of starting the mRNA-1273 pivotal Phase 3 study early this summer.'

Phase 1 Clinical Trials

- NVX-CoV2373 SARS-CoV-2 Vaccine (https://www.precisionvaccinations.com/vaccines/nvx-cov2373-sars-cov-2-vaccine) - May 11, 2020 - Novavax to Receive up to $388 Million Funding from CEPI for COVID-19 Vaccine Development and Manufacturing.
- BNT162 - May 5, 2020 - Pfizer Inc. and BioNTech SE announced that the first participants have been dosed in the U.S. in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19.
- ChAdOx1 nCoV-19 Vaccine (/vaccines/chadox1-ncov-19-vaccine) - April 30, 2020 - AstraZeneca and the University of Oxford announced an agreement for the global

development and distribution of the recombinant adenovirus vaccine aimed at preventing COVID-19 disease from SARS-CoV-2 coronavirus infections.

- NVX-CoV2373 (/vaccines/nvx-cov2373-sars-cov-2-vaccine) - April 8, 2020, Novavax, Inc. announced it has identified a coronavirus vaccine candidate, a stable, prefusion protein made using Novavax's proprietary nanoparticle technology and will initiate a first-in-human trial in mid-May. NVX-CoV2373 was shown to be highly immunogenic in animal models measuring spike protein-specific antibodies, antibodies that block the binding of the spike protein to the receptor, and wild-type virus-neutralizing antibodies.

- INO-4800 DNA Coronavirus Vaccine (/vaccines/ino-4800-dna-coronavirus-vaccine) - April 30, 2020 - INOVIO announced it has entered into an agreement to expand its manufacturing partnership with the German contract manufacturer Richter-Helm BioLogics GmbH & Co. KG, to support large-scale manufacturing of INOVIO's investigational DNA vaccine INO-4800, which currently is in Phase 1 clinical testing in the U.S. for COVID-19 and could potentially advance to Phase 2/3 efficacy trials this summer.

- Adenovirus Type 5 Vector vaccine candidate (/vaccines/ad5-ncov-covid-19-vaccine) ("Ad5-nCoV"), co-developed by CanSinoBIO and Beijing Institute of Biotechnology, was approved to enter into Phase 1 Clinical Trial on March 17, 2020. April 9, 2020, based on the preliminary safety data of phase I clinical trial, the company plans to initiate phase II clinical trial for Ad5-nCoV in China soon.

- Johnson & Johnson announced (/vaccines/covid-19-janssen-vaccine) the selection of a lead COVID-19 vaccine candidate and expects to initiate human clinical studies by September 2020 and anticipates the first batches of a COVID-19 vaccine that could be available for Emergency Use Authorization in early 2021. J&J expects to rapidly scale the manufacturing capacity with the goal of providing more than 1 billion doses of a coronavirus vaccine.

- Sanofi and GSK (https://www.precisionvaccinations.com/vaccines/sanofi-gsk-sars-cov-2-vaccine) to join forces in unprecedented vaccine collaboration to fight COVID-19. Candidate vaccine expected to enter clinical trials in the second half of 2020 and, if successful, to be available in the second half of 2021

May 2020: SARS-CoV-2 Coronavirus Vaccine Development News

May 12, 2020 - GreenLight Biosciences announced it has closed a $17M special purpose funding round to build out its scalable mRNA production capability targeting the production of billions of doses of COVID-19 vaccine. In addition to expanding its manufacturing capacity, GreenLight is developing several differentiated mRNA vaccine candidates against SARS-CoV2, the virus responsible for COVID-19.

May 11, 2020 - Novavax, Inc. announced that the Coalition for Epidemic Preparedness Innovations will invest up to $384 million of additional funding, on top of $4 million it invested in March, to advance the clinical development of NVX-CoV2373, Novavax' coronavirus vaccine candidate against the SARS-CoV-2 coronavirus.

May 11, 2020 - Themis and ABL Europe announced today that they have signed an agreement under which ABL will manufacture Themis' SARS-CoV-2 vaccine candidate in preparation for clinical trials. The vaccine is being developed using a proprietary measles virus vaccine platform technology, which is licensed exclusively to Themis by the Institut Pasteur in Paris.

May 8, 2020 - Arcturus Therapeutics Holdings Inc. announced new supportive preclinical data, providing evidence for an adaptive cellular (CD8+ cells) and balanced (Th1/Th2) immune response data from the Company's COVID-19 vaccine program (LUNAR-COV19). These new results augment previously disclosed preclinical data demonstrating a strong antibody response (anti-spike protein IgG and 100% virus neutralization at a very low vaccine dose) from the

program.

May 7, 2020 - Translate Bio announced the Sanofi Pasteur collaboration pursuing the development of a novel mRNA vaccine for COVID-19. Multiple COVID-19 vaccine candidates are being evaluated in vivo for immunogenicity and neutralizing antibody activity to support lead candidate selection and the companies have the goal of initiating a first-in-human clinical trial in the fourth quarter of 2020.

May 6, 2020 - A new pilot-scale production of a purified inactivated SARS-CoV-2 virus vaccine candidate (PiCoVacc), reported it induced SARS-CoV-2-specific neutralizing antibodies in mice, rats, and non-human primates. These antibodies neutralized 10 representative SARS-CoV-2 strains, suggesting a possible broader neutralizing ability against SARS-CoV-2 strains. Three immunizations using two different doses (3 μg or 6 μg per dose) provided partial or complete protection in macaques against the SARS-CoV-2 challenge, respectively, without observable antibody-dependent enhancement of infection.

May 4, 2020 – Arcturus Therapeutics and Catalent announced a partnership to support the expected manufacture of Arcturus' COVID-19 mRNA vaccine candidate (LUNAR-COV19), intended to protect against the SARS-CoV-2 coronavirus. LUNAR-COV19 utilizes Arcturus' self-transcribing and replicating mRNA (STARR™) technology and the Company's LUNAR® lipid-mediated delivery to produce an extraordinarily low dose, potential single shot COVID-19 vaccine.

April 2020: SARS-CoV-2 Coronavirus Vaccine Development News

April 30, 2020 - Vaxart, Inc. announced that it has obtained positive pre-clinical results for its COVID-19 vaccine candidates. In January 2020, Vaxart initiated a program to develop a COVID-19 vaccine based on its VAASTTM oral vaccines platform. In this second round of preclinical testing, all animals received two doses of the Vaxart vaccines, two weeks apart. Antibody responses in all vaccinated groups were statistically significant compared to the untreated controls.

April 28, 2020 - Dr. Jeffrey Cirillo at the Texas A&M Health Science Center is leading a group of world-renown institutions in a phase 4 BCG vaccine clinical trial that could prevent COVID-19 disease cases in just 6-months. This phase 4 vaccine study will include 1,800 participants and researchers from Harvard's School of Public Health, the University of Texas MD Anderson Cancer Center in Houston, Cedars Sinai Medical Center in Los Angeles, and the Baylor College of Medicine in Houston.

April 27, 2020, Moderna, Inc. announced that it has submitted an application to the U.S. FDA for the company's mRNA vaccine candidate (mRNA-1273), which is targeted against the SARS-CoV-2 coronavirus, to be evaluated in Phase 2 and late-stage clinical studies.

April 23, 2020 - Emergent BioSolutions Inc. announced an agreement whereby Emergent will deploy its contract development and manufacturing services to support the manufacturing of J&J's lead vaccine candidate for COVID-19 that leverages the AdVac® and PER.C6® technologies from the Janssen Pharmaceutical Companies of J&J.

April 23, 2020 - ReiThera, LEUKOCARE, and Univercells announce pan-European consortium for the fast-track development of a single-dose adenovirus-based COVID-19 vaccine.

April 22, 2020 – Valneva SE and Dynavax Technologies Corporation announced their collaboration to initiate a vaccine program for the current coronavirus, COVID-19. Valneva is leveraging its technology and platform capabilities to develop an inactivated, whole virus vaccine candidate against the current coronavirus threat. Dynavax is providing CpG 1018, the adjuvant contained in U.S. FDA-approved HEPLISAV-B vaccine, to support the development of Valneva´s COVID-19 vaccine candidate.

April 21, 2020 - UK health secretary Matt Hancock announced human trials of a potential coronavirus vaccine developed at Oxford University are to begin on Thursday. The team will enroll healthy volunteers aged between 18 – 55, who, if they pass screening, will be the first humans to test the new vaccine, called ChAdOx1 nCoV-19.

April 21, 2020 - Vaxart, Inc. announced that it has obtained positive pre-clinical results for its COVID-19 vaccine candidates, with several of the vaccine candidates generating immune responses in all tested animals after a single dose. On March 18, 2020, Vaxart entered into an agreement with Emergent BioSolutions Inc. for development services to prepare for cGMP production of an oral COVID-19 vaccine.

April 16, 2020 - Dynavax Technologies and Sinovac Biotech Ltd. announced that they have entered into a collaboration to evaluate the combination of Sinovac's chemically inactivated coronavirus vaccine candidate, with Dynavax's advanced adjuvant, CpG 1018 ™.

April 16, 2020 - The Coalition for Epidemic Preparedness Innovations has granted $6.9 million funding to INOVIO to work with the Korea National Institute of Health for a Phase 1/2 clinical trial of INOVIO's COVID-19 vaccine candidate (INO-4800) in South Korea.

April 14, 2020 - Sanofi and GSK join forces in unprecedented vaccine collaboration to fight COVID-19 disease. Sanofi will contribute its S-protein COVID-19 antigen, which is based on recombinant DNA technology. GSK will contribute its proven pandemic adjuvant technology to the collaboration.

April 14, 2020 – NantKwest and ImmunityBio, Inc., clinical-stage immunotherapy companies within the NantWorks family of companies, announced they are in active discussions with the U.S. FDA for vaccines and therapeutics to combat COVID-19.

April 8, 2020 - Novavax, Inc. announced it has identified a coronavirus vaccine candidate, NVX-CoV2373, a stable, prefusion protein made using Novavax' proprietary nanoparticle technology, and will initiate a first-in-human trial in mid-May. Novavax' proprietary Matrix-M™ adjuvant will be incorporated with NVX-CoV2373 in order to enhance immune responses and stimulate high levels of neutralizing antibodies.

April 6, 2020 - OncoSec Medical Incorporated announced that Providence Cancer Institute is pursuing a first-in-human Phase 1 clinical trial of OncoSec's novel DNA-encodable, investigational vaccine, CORVax12, which is designed to act as a prophylactic vaccine to prevent COVID-19. CORVax12 consists of OncoSec's existing product candidate, TAVO™ (interleukin-12 or "IL-12" plasmid), in combination with an immunogenic component of the SARS-CoV-2 virus recently developed by researchers at NIH's National Institute of Allergy and Infectious Diseases ("NIAID") and licensed to OncoSec on a non-exclusive basis.

April 2, 2020 - University of Pittsburgh School of Medicine scientists today announced a potential vaccine against SARS-CoV-2, the new coronavirus causing the COVID-19 pandemic. When tested in mice, the vaccine, delivered through a fingertip-sized patch, produces antibodies specific to SARS-CoV-2 at quantities thought to be sufficient for neutralizing the virus. The paper appeared today in EBioMedicine, which is published by The Lancet and is the first study to be published after critique from fellow scientists at outside institutions that describes a candidate vaccine for COVID-19.

April 2, 2020 – Applied DNA Sciences Inc. and Takis Biotech announced an expansion of their COVID-19 vaccine development program to include a 5th vaccine candidate. Production of all vaccine candidates is expected to be completed this month. All vaccine candidates have also been approved by Italy's Ministry of Health for preclinical animal testing that is scheduled to begin in late April 2020.

MERS-CoV Coronavirus Vaccine Candidates Conducting Human Clinical Trials

- **INO-4700 MERS-CoV is a DNA plasmid vaccine (/vaccines/ino-4700-mers-cov-vaccine-0)** that expresses the MERS CoV spike (S) glycoprotein. Inovio expects to advance INO-4700 into a Phase 2 field study in the Middle East and Africa where outbreaks have been observed, with full funding from CEPI. On January 6, 2020, the company says this is

the most advanced vaccine candidate for MERS. The Wistar Institute announced January 23, 2019, that they are part of the Inovio team. Wistar brings the experience and suitability of its DNA technology platform to rapidly translate a vaccine against an emerging virus.

- **GLS-5300** (/vaccines/gls-5300-mers-cov-vaccine)**MERS-CoV Vaccine (/vaccines/gls-5300-mers-cov-vaccine)** - The GLS-5300 MERS-CoV product is a DNA vaccine candidate, which allows for rapid design and production in response to emerging infectious diseases. Underscoring the potential for rapid deployment of DNA vaccines, GLS-5300 was advanced into the clinic within nine months of preclinical vaccine candidate selection. GLS-5300 was co-developed by GeneOne Life Science Inc. and Inovio Pharmaceuticals. GLS-5300 is administered intramuscularly using the CELLECTRA® delivery device. A July 24, 2019, Phase 1 first-in-human clinical trial. Initial findings from the trial were published in *The Lancet Infectious Diseases*.

- **ChAdOx1 MERS-CoV Vaccine (/vaccines/chadox1-mers-mers-cov-vaccine)** - ChAdOx1 MERS is a vaccine candidate to treat Middle East Respiratory Syndrome Coronavirus (MERS-CoV). The ChAdOx1 MERS vaccine consists of the replication-deficient simian adenovirus vector ChAdOx1, containing the MERS Spike protein antigen. The first-in-human trial is now being conducted in Oxford in UK healthy adult volunteers. The vaccine will be administered intramuscularly. This is an open-label, dose-escalation phase 1b trial to assess the safety and immunogenicity of the candidate ChAdOx1 MERS vaccine in healthy Middle Eastern adult volunteers aged 18-50.

- **MVA MERS (/vaccines/mva-mers-vaccine)** (Modified Vaccinia virus Ankara) is a vaccine candidate that contains the full-length spike gene of MERS-CoV. MVA MERS vaccines are produced with tPA, but either the mH5 or F11 promoter driving expression of the spike gene. In this phase I first-in-human clinical trial, healthy volunteers in two different dose cohorts will be vaccinated twice with the candidate vaccine MVA-MERS-S. A subgroup will additionally receive a late booster vaccination. A second phase 1b study is a two-center study in approximately 160 healthy adults aged 18-55 years. The study is to assess the safety and immunogenicity of MVA-MERS-S_DF-1.

Coronavirus Vaccine Development Overview

There are 5 approaches currently being taken by various organizations deploying different technologies to develop a vaccine against SARS-CoV-2.

Vaccines based on whole, inactivated SARS-CoV, spike subunits, recombinant viruses expressing

SARS-CoV proteins, DNA plasmids expressing SARS-CoV proteins, or virus-like particles (VLPs) have all been tested in vitro and in vivo.

Coronavirus FAQs

- Updated Coronavirus FAQs
- Canada
- CDC
- PAHO
- UK
- WHO

COVID-19 disease outbreak news is available at **CoronavirusToday.com**

Note: Content sources on this webpage include, but are not limited to, the WHO, the CDC, industry studies, and clinicalTrials.gov. The content was Fact-Checked by Dr. Robert Carlson and other healthcare professionals. Precision Vax's digital network includes CoronavirusToday.com, PrecisionVaccinations.com (https://www.precisionvaccinations.com/), ZikaNews.com, and Vax-Before-Travel.com.

Updated 05/14/2020 - 10:16

VACCINE NEWS

Coronavirus Convalescent Therapy Found Safe in Houston (/houston-methodist-convalescent-serum-therapy-could-be-vital-covid-19-treatment)

Houston Methodist convalescent serum therapy could be a vital COVID-19 treatment (/houston-methodist-convalescent-serum-therapy-could-be-vital-covid-19-treatment)

(/houston-methodist-convalescent-serum-therapy-

Fact checked by Robert Carlson, MD (https://www.precisionvaccinations.com/people/robert-c
(/people/robert-carlson-md)

30 Million Very-Reliable Coronavirus Tests Shipping in May (/abbott-sars-cov-2-igg-lab-based-serology-blood-tests-begin-mass-distribution)

Abbott SARS-CoV-2 IgG lab-based serology blood tests begin mass distribution (/abbott-sars-cov-2-igg-lab-based-serology-blood-tests-begin-mass-distribution)

(/abbott-sars-cov-2-igg-lab-based-serology-blood-tests-begin-mass-distribution)

Fact checked by Robert Carlson, MD (https://www.precisionvaccinations.com/people/robert-c
(/people/robert-carlson-md)

Coronavirus Vaccine Candidate Gains a French Partner (/abl-europe-will-manufacture-themis-sars-cov-2-vaccine-candidate)

ABL Europe will manufacture Themis SARS-CoV-2 vaccine candidate (/abl-europe-will-manufacture-themis-sars-cov-2-vaccine-candidate)

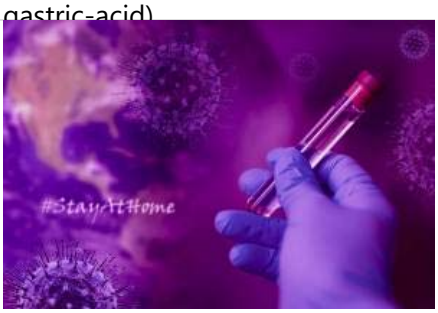
(/abl-europe-will-manufacture-themis-sars-cov-2-vaccine-candidate)

Fact checked by Robert Carlson, MD (https://www.precisionvaccinations.com/people/robert-c
(/people/robert-carlson-md)

Heartburn Drug Decreased COVID-19 Disease Fatalities (/famotidine-pepcid-ingredient-which-treats-heartburn-and-gastric-acid)

Famotidine is a Pepcid ingredient which treats heartburn and gastric acid (/famotidine-pepcid-ingredient-which-treats-heartburn-and-gastric-acid)

(/famotidine-pepcid-ingredient-which-treats-heartburn-and-gastric-acid)



Fact checked by Danielle Reiter, RN (https://www.precisionvaccinations.com/people/danielle-
(/people/danielle-reiter-rn)

Rutgers Home Saliva Test for Coronavirus Approved (/rutgers-taqpath-sars-cov-2-assay-approved-home-saliva-tests)

Rutgers TaqPath SARS-CoV-2 Assay approved for home saliva tests (/rutgers-taqpath-sars-cov-2-assay-approved-home-saliva-tests)

(/rutgers-taqpath-sars-cov-2-assay-approved-home-saliva-tests)

VACCINE DATA

Condition: Coronavirus

BIG STORIES

Heartburn Drug Decreased COVID-19 Disease Fatalities

(/famotidine-

For Certain Children, 2 Flu Shots Confer Better Protection

which
(/influenza-
treats-

Lyme Disease Vaccine Gains Global Partner

fatalities-
gastric-
valneva-
reached-

Phase 4 Study Launches in Texas To Prevent Coronavirus Disease

vaccine-
2020-flu-
vials-
texas-

Influenza Vaccination Reduces Unnecessary Antibiotic Prescriptions

surface-
(/flu-
anderson-
protein-
shots-
covid-19-
osha-
reduce-
prevention-
borrelia)
antibiotic-
study-
use-
uses-
ambulatory-
approved-
care)
tuberculosis-
vaccine)

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