

UPDATE DEVELOPMENT OF COVID 19 VACCINES

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Providers dealing with the COVID-19 outbreak grapple with an influx of patients, shifting guidelines, and dwindling supplies of protective gear. They are worried for their safety and that of their families, yet they are inspired to keep serving patients.

Initial identification of novel coronavirus disease (COVID-19) in Wuhan, China was alerted by the ophthalmologist Li Wenliang in December, 2019 after reporting unusual cases of pneumonia. Believed to be linked with Wuhan seafood market, it has spread to more than 166 countries in the world, and declared a pandemic by the WHO, evolving from an epidemic to pandemic in just 45 days (Fauci, Lane, & Redfield, 2020). As of today, April 20, 2020 U.S. Covid-19 cases are 746,625 and reported deaths are 39,083. The actual numbers may be higher and are still rising (Center for Disease Control, 2020). The global incidence Covid-19 as reported by the World Health Organization (WHO) is 2,314,621 confirmed cases and 157,847 deaths and continues to rise (World Health Organization, 2020).



At present, no specific antiviral treatment and no efficient vaccines are available for COVID-19 in humans. Recently, two familiar broad-spectrum antiviral drugs remdesivir and favipiravir have been tested against clinical isolate of COVID-2019 in vitro with non-confirmatory results (Panati & Narala, 2020).

As the Covid-19 pandemic begins to peak worldwide, with hotspots in New York, New Jersey, Florida, Washington, and Louisiana, the development of vaccines has been a priority. Days after the outbreak, scientists sequenced the genome of the virus and developed several promising vaccine candidates. Bill Gates reports in the New England Journal of Medicine (NEJM) the Coalition for Epidemic Preparedness Innovations (CEPI) (established in 2016 in response to the W. African Ebola outbreak with the goal to develop vaccines to prevent worldwide pandemics by partnering with international stakeholders in government, business, and humanitarian organizations) is currently preparing up to eight promising vaccines for clinical trials.

If some of these vaccines prove safe and effective in animals, they could be ready for larger-scale trials as early as June, 2020. Gates proposes that governments and industry must work together so these life-saving vaccines and antivirals aren't sold to the highest bidder but be made available and affordable to all people who are affected by the pandemic (Gates, 2020).

The past epidemics of H1N1 influenza, Ebola, Zika, and now SARS-CoV-2 (Covid-19) have required the scientific community and the vaccine industry to respond urgently to epidemics. Funding the research and development of vaccines can be costly and often not lucrative to commercial markets. CEPI is an international non-governmental organization funded by the Wellcome Trust, the Bill and Melinda Gates Foundation, the European Commission, and eight countries (Australia, Belgium, Canada, Ethiopia, Germany, Japan, Norway, and the United

Kingdom) (Gouglas et al., 2019) that is supporting development of vaccines against five epidemic pathogens on the World Health Organization (WHO) priority list (Gouglas et al., 2019).

RNA and DNA vaccines can be made quickly because they do not require culture or fermentation, using synthetic processes. There are no approved RNA vaccines to date, but RNA vaccines have entered clinical trials for Covid-19 (Lurie, Saville, Hatchett, & Halton, 2020).

Whether a single-dose vaccine will confer immunity is uncertain, as well as the potential duration of immunity.



Vaccine development typically is a lengthy, expensive process. Selected clinical trials of vaccines currently underway include the following shown in the table below (there are many vaccine trials underway, too many to show in this article) (Lurie et al., 2020). For updates on Covid-19 clinical trials for vaccines, visit <https://clinicaltrials.gov/ct2/show/NCT04341389> (NIH U.S. National Library of Medicine, 2020). ●

CLINICAL TRIAL VACCINE FRONTRUNNERS:	SPONSOR	STUDY TIMELINE:	OTHER
Lipid nanoparticles containing mRNAs for the SARS-CoV-2 spike protein are injected into the arm.	Moderna and the US Government	Phase I trial underway in Seattle, WA	
Nonreplicating adenovirus 5 (Ad5) vector carrying the gene for the SARS-CoV-2 spike protein is injected into the arm.	CanSino Biologics and the Academy of Military Medical Sciences, China	Phase 1 clinical trial underway in Wuhan, China	
Sarilumab in Hospitalized Patients With COVID-19	Regeneron Pharmaceuticals	March 18, 2020- April 1, 2021	
A Single-center, Open-label, Dose-escalating Phase I Clinical Trial to Evaluate Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) in Healthy Adults Aged 18-60 Years Old	CanSino Biologics Inc.	March 16, 2020 - December 20, 2022	

CLINICAL TRIAL VACCINE FRONTRUNNERS:	SPONSOR	STUDY TIMELINE:	OTHER
A phase I/II single-blinded, randomised, placebo controlled, multi-center study to determine efficacy, safety and immunogenicity of the candidate Coronavirus Disease (COVID-19) vaccine ChAdOx1 nCoV-19 in UK healthy adult volunteers aged 18-55 years. The vaccine will be administered intramuscularly (IM).	University of Oxford	April 2020 - May 2021	
Chloroquine Phosphate Against Infection by the Novel Coronavirus SARS-CoV-2: The HOPE Open-Label, Non-Randomized Clinical Trial	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	April 6, 2020 - April 30, 2021	Chloroquine phosphate (200mg).

Center for Disease Control. (2020). 2019 Novel Coronavirus. Retrieved from Public Health Media Library website: <https://tools.cdc.gov/medialibrary/index.aspx#/feed/id/403372>

Fauci, A. S., Lane, H. C., & Redfield, R. R. (2020). Covid-19—navigating the uncharted. Retrieved from Gates, B. (2020). Responding to Covid-19—a once-in-a-century pandemic? New England Journal of Medicine.

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