

NIH Advisory Committee to the Director

Overview of COVID-19 and the Research Response

Anthony S. Fauci, M.D.

Director

**National Institute of Allergy and
Infectious Diseases**

National Institutes of Health

June 11, 2020



Science

January 3, 2020

Novel Human Virus? Pneumonia Cases Linked to Seafood Market in China Stir Concern

By Dennis Normile

The Washington Post

January 9, 2020

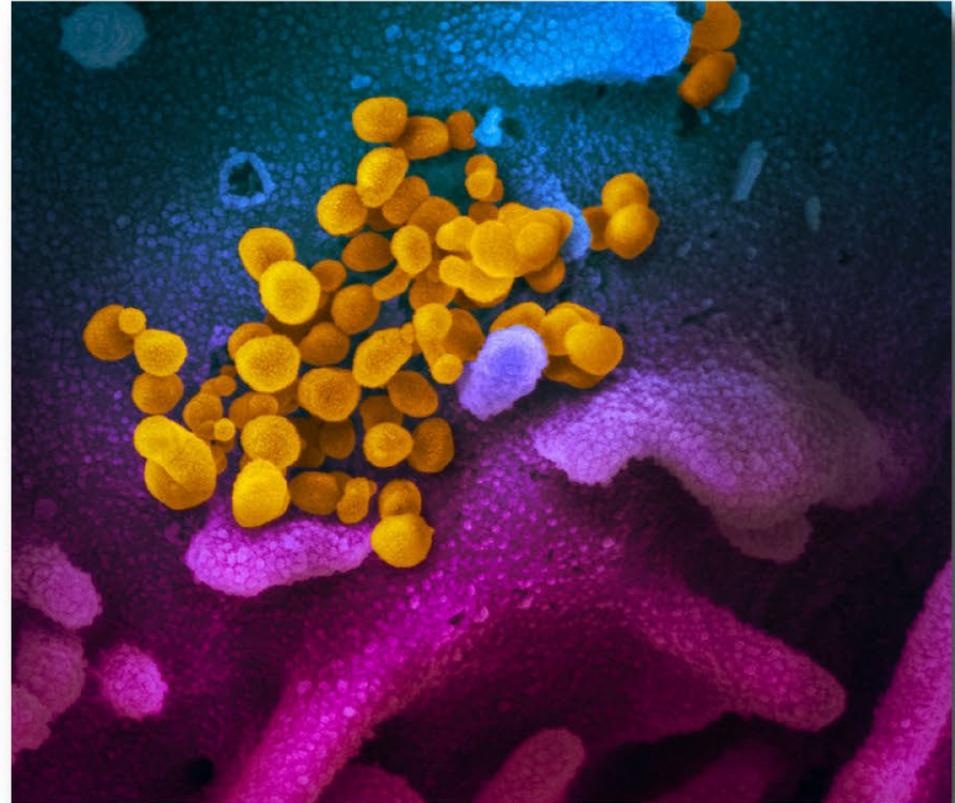
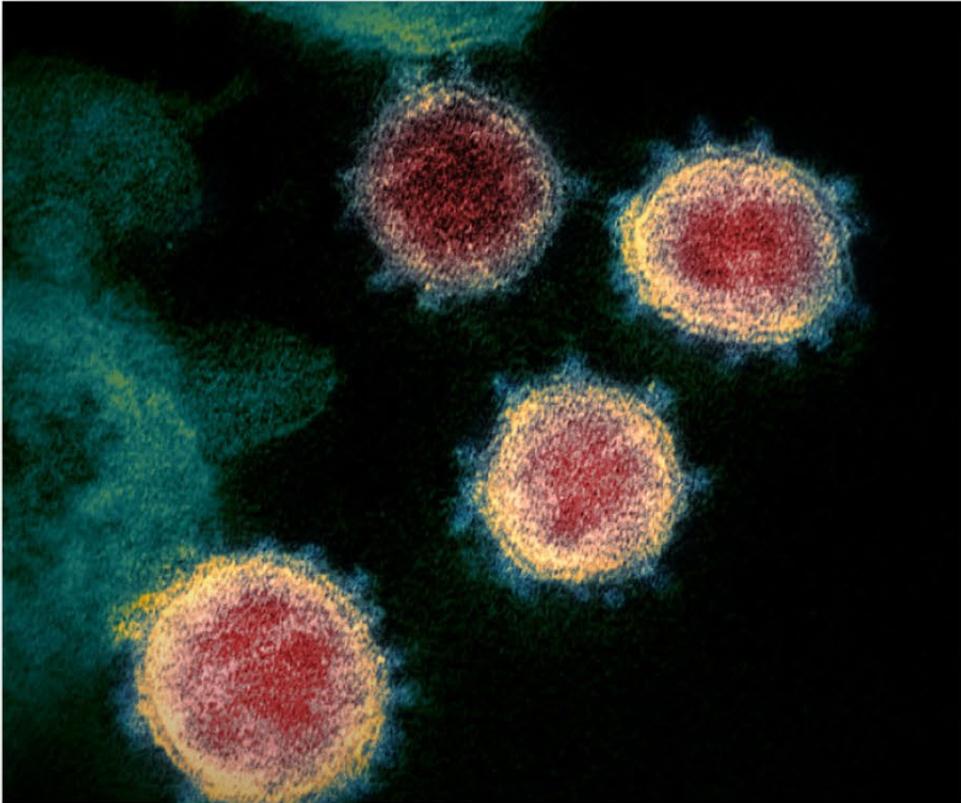
Washington Post: China Identifies New Strain of Coronavirus as Source of Pneumonia Outbreak

Health officials run thermal scans on passengers arriving from Wuhan, China, at Bangkok's Suvarnabhumi Airport on Wednesday.

By Gerry Shih and Lena H. Sun

Coronavirus Disease 2019 (COVID-19) (December 2019 – Present)

- **COVID-19 is caused by the novel coronavirus SARS-CoV-2**



The Washington Post

January 17, 2020

Travelers at 3 U.S. Airports to Be Screened for New, Potentially Deadly Chinese Virus

January 21, 2020

U.S. Screenings for the Coronavirus Expanded to Airports in Atlanta and Chicago





Centers for Disease Control and Prevention

Press Release

January 21, 2020

First Travel-related Case of 2019 Novel Coronavirus Detected in United States



Centers for Disease Control and Prevention

Press Release

February 26, 2020

CDC Confirms Possible Instance of Community Spread of COVID-19 in U.S.

The Centers for Disease Control and Prevention (CDC) has confirmed an infection with the virus that causes COVID-19 in California in a person who reportedly did not have relevant travel history or exposure to another known patient with COVID-19.

March 3: President Trump Visits NIH Vaccine Research Center



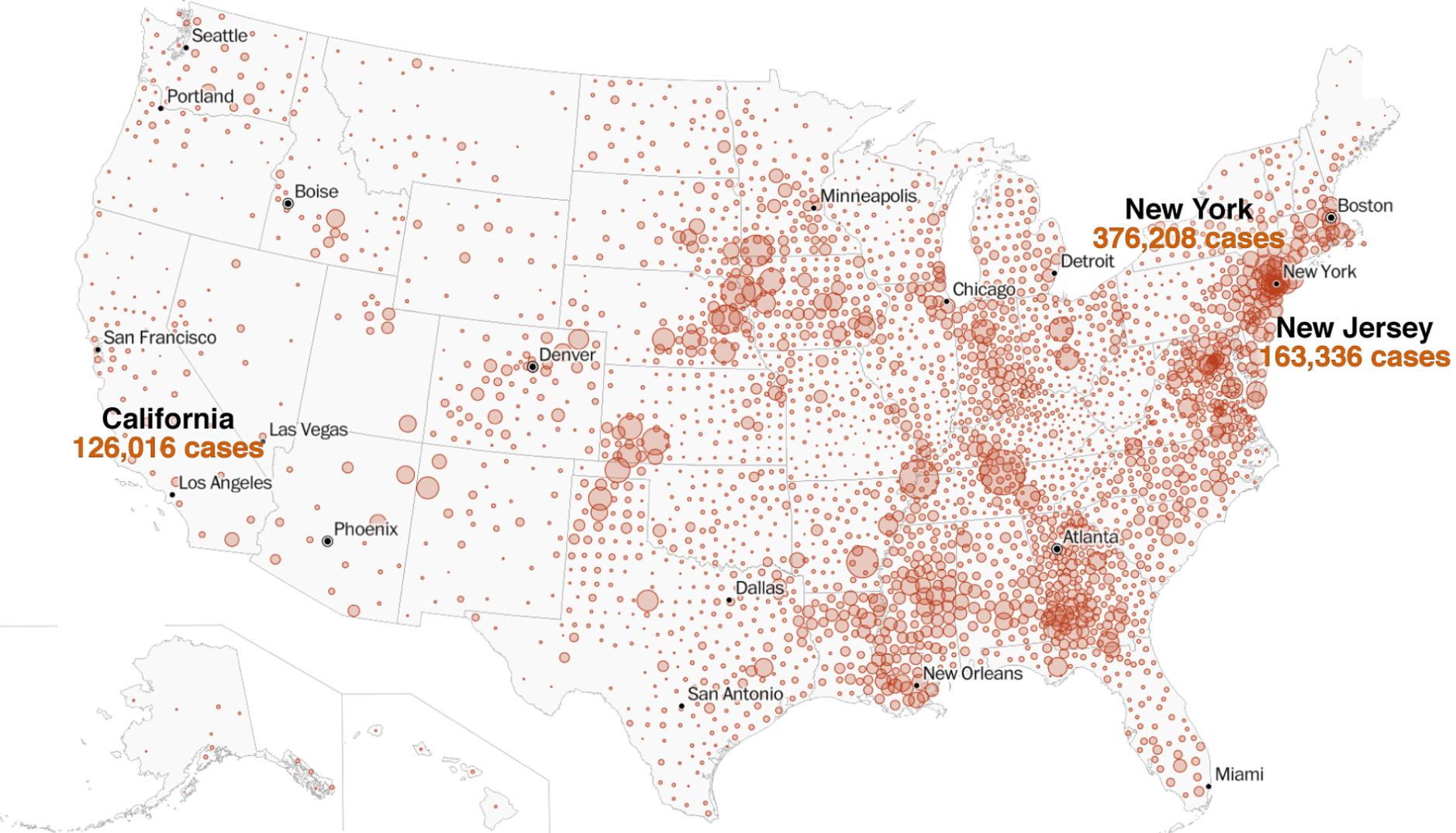
PBS **NEWSHOUR**

March 22, 2020

New York to Shut Down As It Becomes Next Virus Hot Spot



Reported COVID-19 Cases and Deaths in the United States



Reported cases:

1,971,399

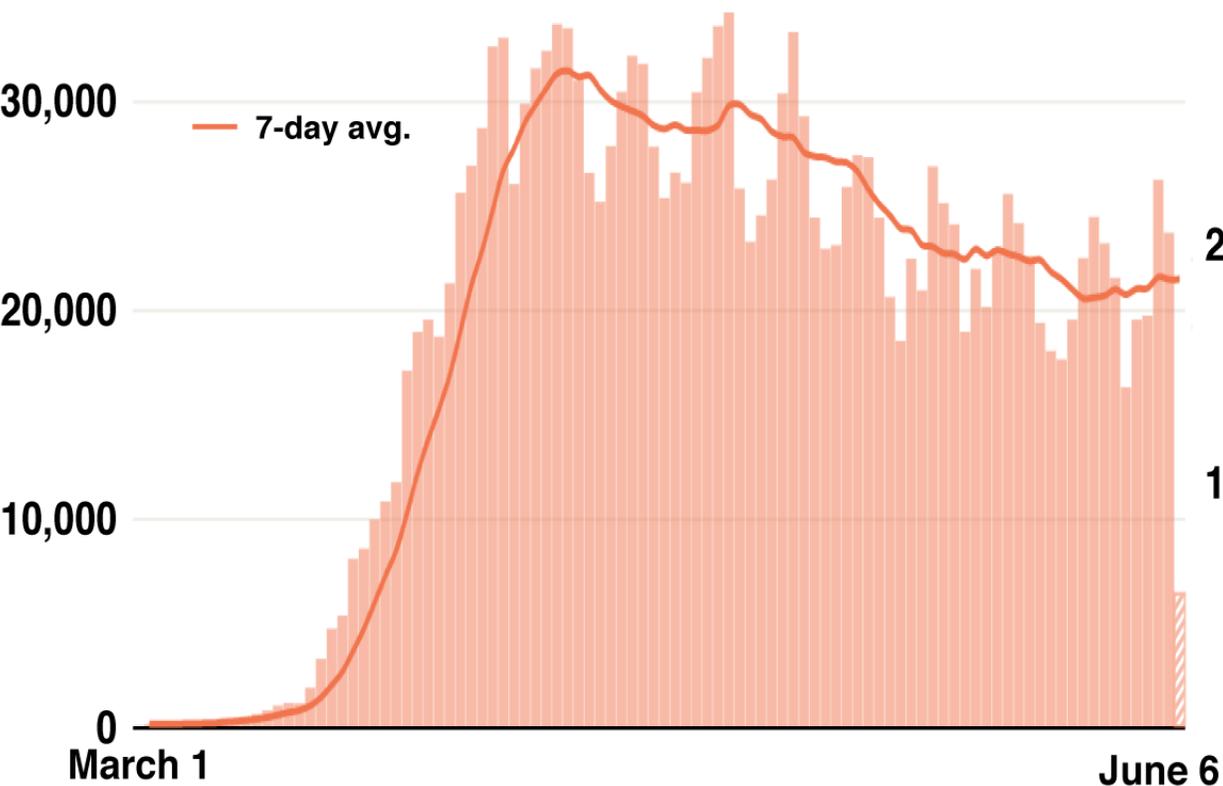
Reported deaths:

111,491

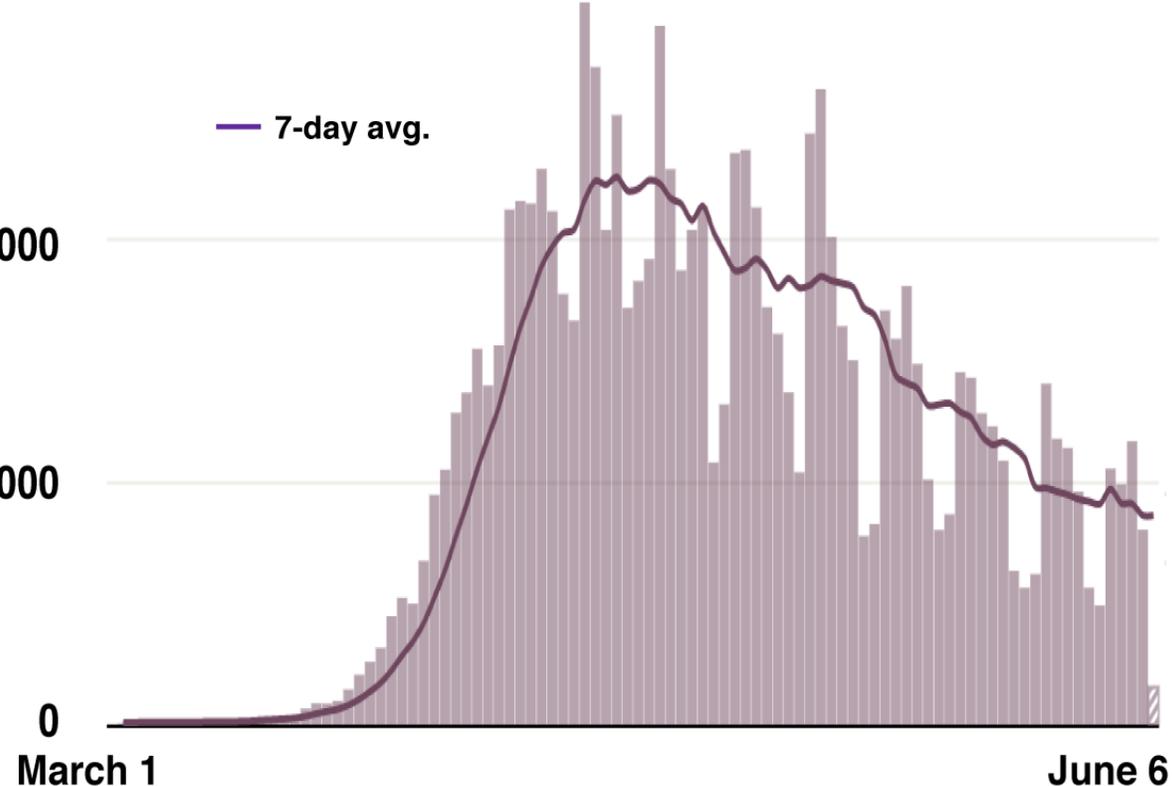
Sources: *Washington Post*, Worldometer. Data as of 6/6/2020, 11:00 am

Reported COVID-19 Cases and Deaths in the United States

Reported cases per day



Reported deaths per day



Graphics: *Washington Post*. Data as of 6/6/2020, 11:00 am

COVID-19 Clinical Presentation

■ Fever	83–99%
■ Cough	59–82
■ Fatigue	44–70
■ Anorexia	40–84
■ Shortness of breath	31–40
■ Myalgias	11–35

Other non-specific symptoms reported

- Sore throat, nasal congestion, headache, diarrhea, nausea, vomiting. Loss of smell/taste preceding the onset of respiratory symptoms.

COVID-19: Wide Spectrum of Disease

Asymptomatic Illness No symptoms

Mild Illness Uncomplicated upper respiratory tract infection

Moderate Disease Pneumonia without the need for supplemental oxygen

Severe Pneumonia Pneumonia plus one of the following: respiratory rate > 30 breaths/min; severe respiratory distress; or SpO₂ $< 90\%$ on room air

Critical Illness ARDS, sepsis, septic shock, multiple organ dysfunction/failure

Prevalence of Asymptomatic SARS-CoV-2 Infection

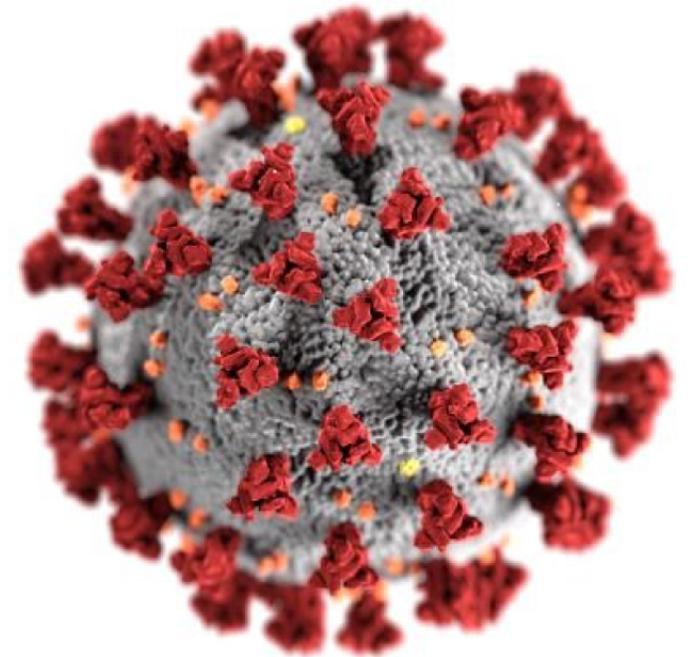
A Narrative Review

DP Oran and EJ Topol

- Data from 16 cohorts, total n= 45,000+
- Asymptomatic persons account for ~40-45% of SARS-CoV-2 infections

Groups at Higher Risk for Severe COVID-19 Illness

- Age >65 years
- People in nursing homes or long-term care facilities
- Asthma
- Chronic kidney disease
- Chronic lung disease
- Diabetes
- Hemoglobin disorders
- Immunocompromised
- Liver disease
- Serious heart disease
- Obesity (BMI ≥ 40)



May 11, 2020

JAMA

The Journal of the American Medical Association

Viewpoint

COVID-19 and Racial/Ethnic Disparities

MW Hooper, AM Nápoles and EJ Pérez-Stable

“The most pervasive disparities are observed among African American and Latino individuals, and where data exist, American Indian, Alaska Native, and Pacific Islander populations.”

COVID-19 Research Response

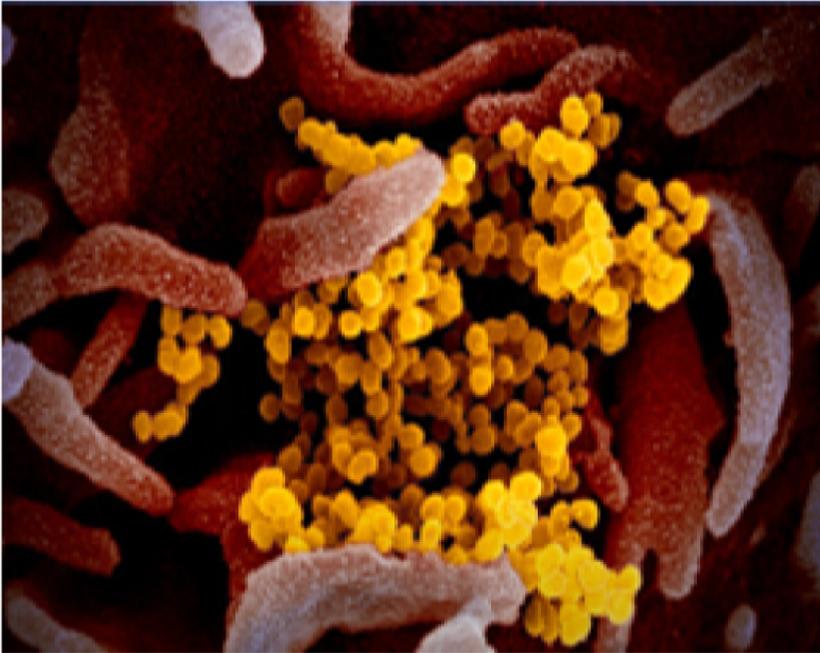
NIH COVID-19 Supplemental Funding

(\$s in millions and are available until 9/30/2024)

<u>NIAID</u>	Basic research, pathogenesis, animal models, epidemiology, diagnostics, vaccines, therapeutics	\$1,532
<u>Other Institutes</u>		\$2,055
<u>NHLBI</u>	Therapeutics and longitudinal studies	103
<u>NIEHS</u>	Worker safety	10
<u>NIBIB</u>	Point-of-care and other rapid testing	560
<u>NLM</u>	Research resources	10
<u>NCATS</u>	Drug screening	36
<u>NIH-OD</u>	Point-of-care and other rapid testing	1,030
<u>NCI</u>	Serological testing and associated technologies	306
Total		\$3,587

NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

APRIL 10, 2020

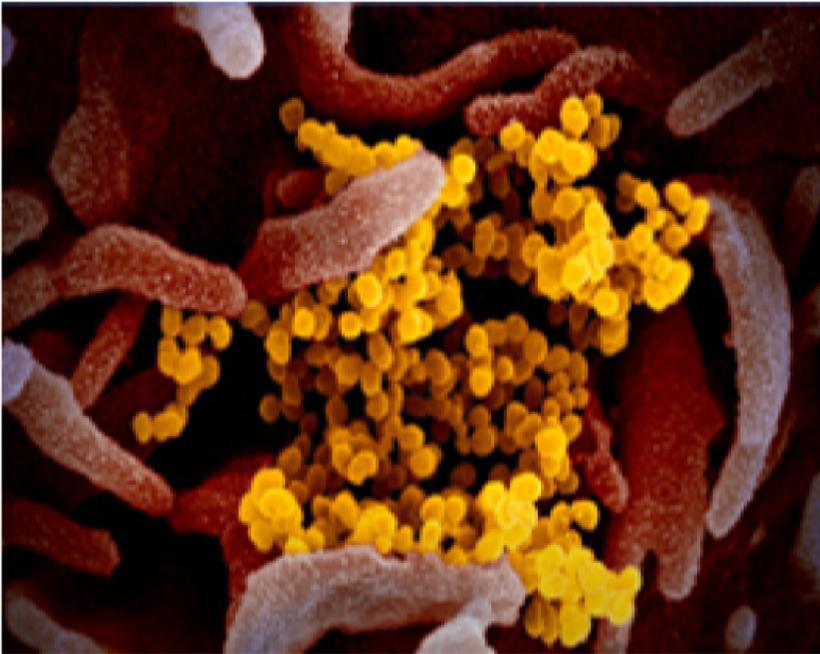


- **Improve fundamental knowledge of SARS-CoV-2 and COVID-19 disease**
- **Develop diagnostics and assays**
- **Characterize and test therapeutics**
- **Develop safe and effective vaccines**



NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

APRIL 10, 2020



- **Improve fundamental knowledge of SARS-CoV-2 and COVID-19 disease**
- **Develop diagnostics and assays**
- **Characterize and test therapeutics**
- **Develop safe and effective vaccines**

Viral Isolates and Reagents Made Available to the Research Community

b | e | i RESOURCES

SUPPORTING INFECTIOUS DISEASE RESEARCH



World Reference Center for Emerging
Viruses and Arboviruses

The University of Texas Medical Branch

Imagining the future at the
Sundance Film Festival p. 1188

Shrinking Colorado River
flow pp. 1192 & 1252

Structure of a key SARS-CoV-2
protein p. 1260

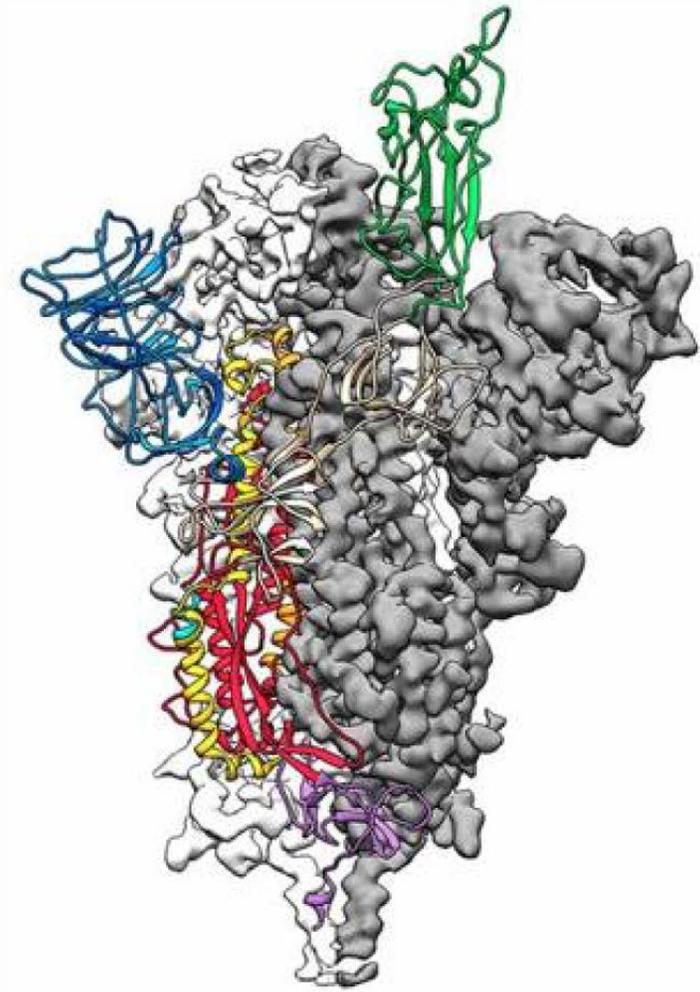
March 13, 2020
Vol. 367 Issue 6483

Science

AAAS

Cryo-EM Structure of the 2019-nCoV Spike in the Prefusion Conformation

D Wrapp, N Wang, KS Corbett, JA Goldsmith,
C-L Hsieh, O Abiona, BS Graham, JS McLellan



Viral membrane

**Atomic-level structure of SARS-CoV-2
spike protein. Receptor binding
domain is colored green.**

April 2020

nature
microbiology

Functional Assessment of Cell Entry and Receptor Usage for SARS-CoV-2 and Other Lineage B Betacoronaviruses

M Letko, A Marzi and V Munster

Uncovering coronavirus entry

- Human ACE2 is the receptor for SARS-CoV-2

Respiratory Disease in Rhesus Macaques Inoculated with SARS-CoV-2

VJ Munster, E de Wit et al.

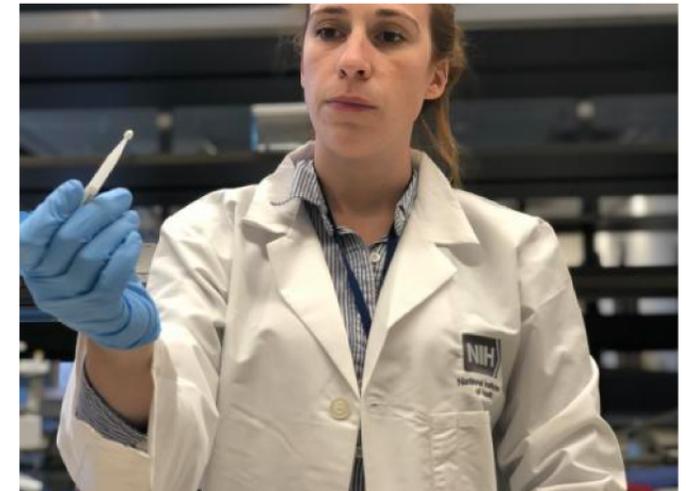
- **Rhesus macaque model recapitulates moderate disease observed in the majority of human COVID-19 cases**



News Release

NIH Begins Study to Quantify Undetected Cases of Coronavirus Infection

***Serological study will provide
insights into which
communities and populations
are most affected by COVID-19***





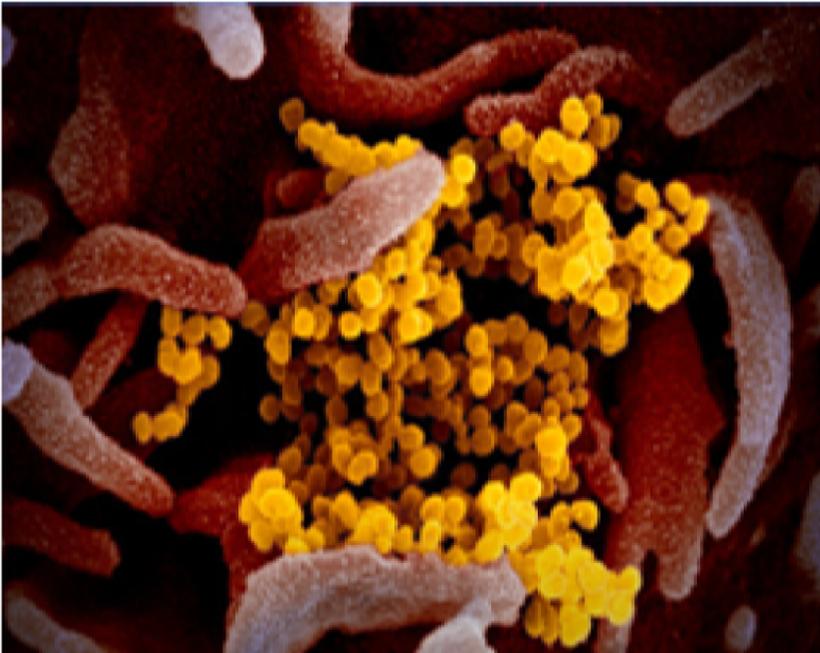
News Release

Study to Determine Incidence of Novel Coronavirus Infection in U.S. Children Begins

- **HEROS study aims to enroll 6,000 people/2,000 families**
- **Study goals are to determine**
 - **The incidence of SARS-CoV-2 in children**
 - **Whether asthma or allergies affect the incidence of infection**
 - **The percentage of infected children who develop COVID-19**

NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

APRIL 10, 2020



- **Improve fundamental knowledge of SARS-CoV-2 and COVID-19 disease**
- **Develop diagnostics and assays**
- **Characterize and test therapeutics**
- **Develop safe and effective vaccines**



News Release

June 4, 2020

Coronavirus (COVID-19) Update: FDA Publicly Shares Antibody Test Performance Data From Kits as Part of Validation Study

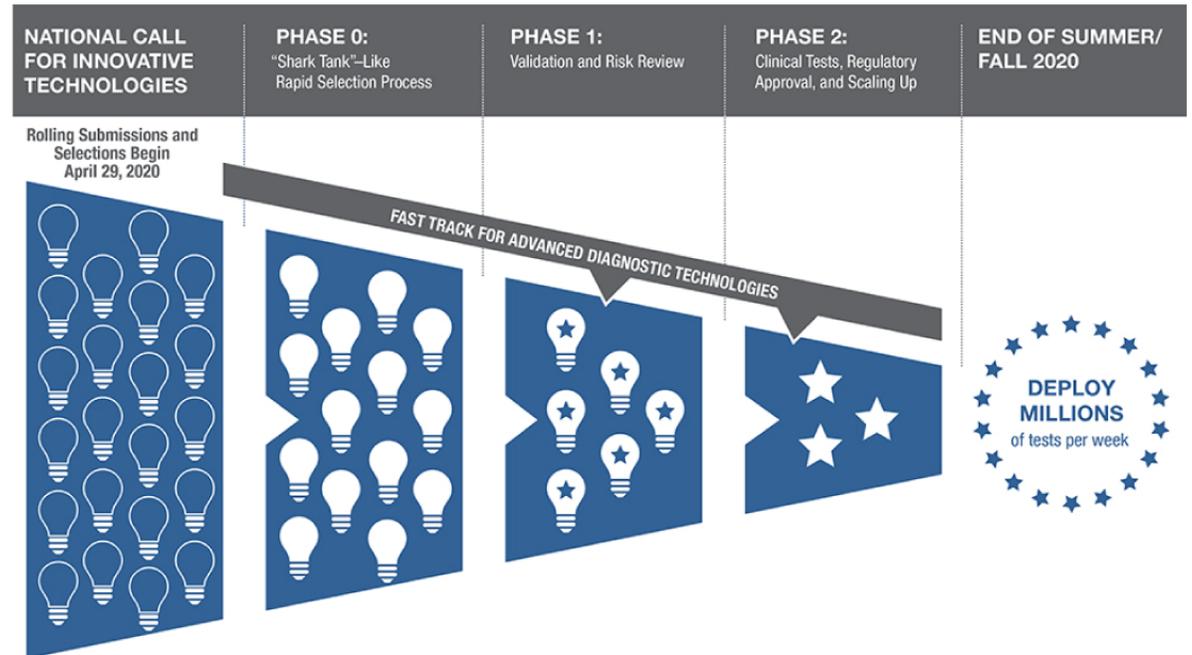
- **Validation study is headed by NCI, with collaboration of NIAID, CDC and BARDA**
- **Includes tests already available as well as those not yet on the market**



News Release

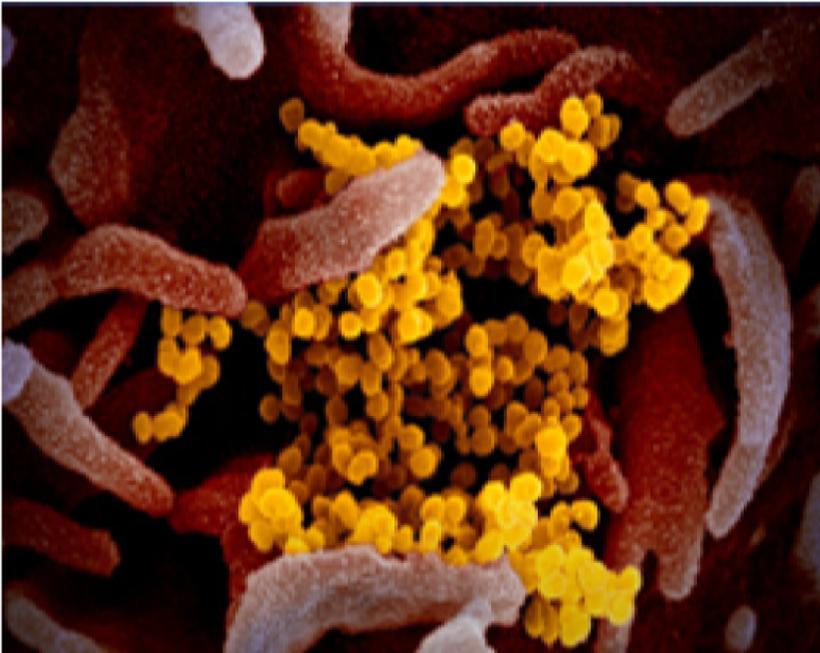
NIH Mobilizes National Innovation Initiative for COVID-19 Diagnostics

- NIH Rapid Acceleration of Diagnostics (RADx) Initiative for COVID-19
- Award up to \$500 million to support development of COVID-19 diagnostics



NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

APRIL 10, 2020



- **Improve fundamental knowledge of SARS-CoV-2 and COVID-19 disease**
- **Develop diagnostics and assays**
- **Characterize and test therapeutics**
- **Develop safe and effective vaccines**



Investigational Therapeutics for COVID-19

- Remdesivir
- Other broad-spectrum antivirals
- Convalescent plasma/hyperimmune immunoglobulin
- Repurposed drugs, e.g. hydroxychloroquine, lopinavir/ritonavir
- Host modifiers/immune-based therapies
- Anti-SARS-CoV-2 monoclonal antibodies
- Others





The
New England
Journal of Medicine

Established in 1812 as THE NEW ENGLAND JOURNAL OF MEDICINE AND SURGERY

published online May 22, 2020

Remdesivir for the Treatment of Covid-19 – Preliminary Report

JH Beigel, HC Lane et al. for the ACTT-1 Study Group Members

- **Patients who received remdesivir had a 32% faster time to recovery than those who received placebo ($p < 0.001$)**
- **Results also suggested a survival benefit**
- **N=1,063 patients from 10 countries in U.S., Europe, Asia**

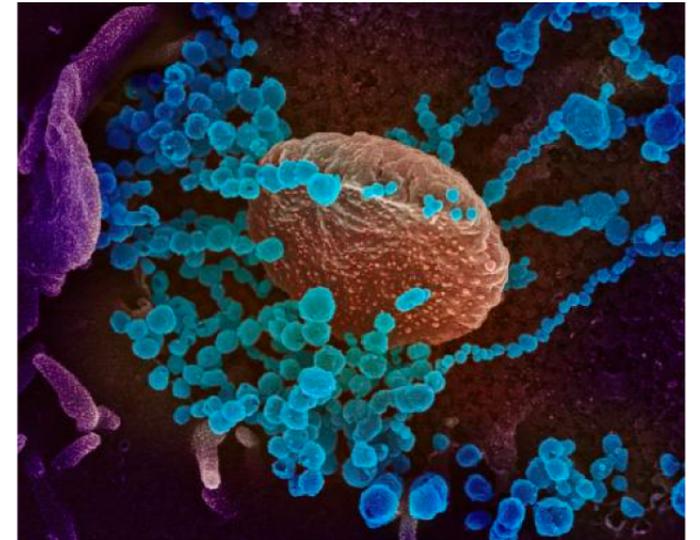


News Release

NIH Clinical Trial Testing Antiviral Remdesivir Plus Anti-Inflammatory Drug Baricitinib for COVID-19 Begins

“ACCT-2 will examine if adding an anti-inflammatory agent to the remdesivir regimen can provide additional benefit for patients, including improving mortality outcomes.”

–Anthony S. Fauci, MD



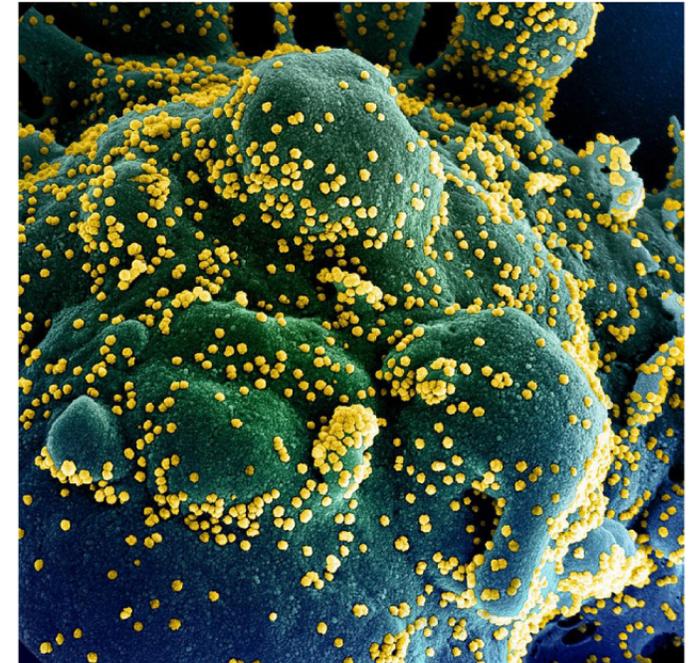


News Release

Expert U.S. Panel Develops NIH Treatment Guidelines for COVID-19

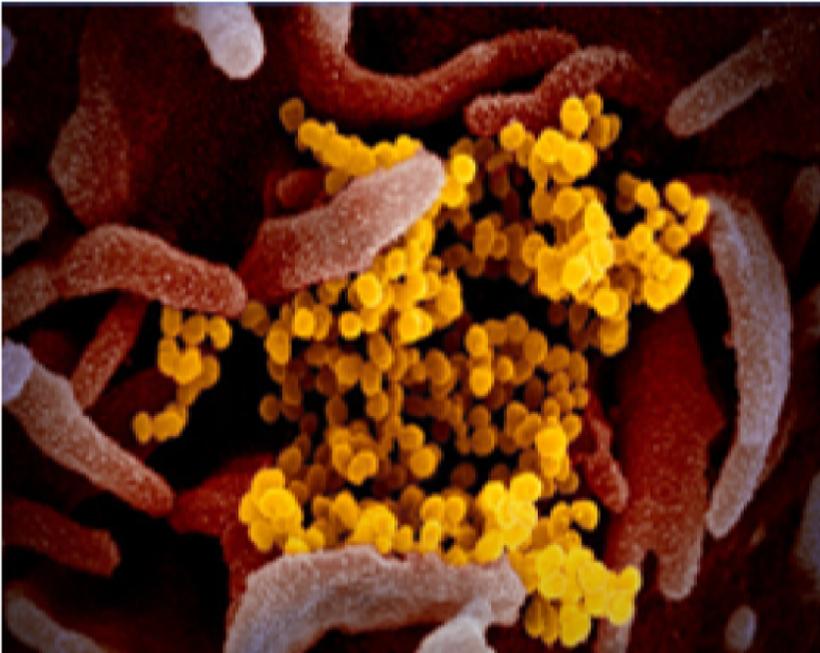
“Living document” expected to be updated often as new clinical data accrue

■ [Covid19treatmentguidelines.nih.gov](https://www.covid19treatmentguidelines.nih.gov)



NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

APRIL 10, 2020



- **Improve fundamental knowledge of SARS-CoV-2 and COVID-19 disease**
- **Develop diagnostics and assays**
- **Characterize and test therapeutics**
- **Develop safe and effective vaccines**



BARDA-Supported COVID-19 Vaccine Candidates

 moderna mRNA

 AstraZeneca  Replication Incompetent Adenovirus (ChAdOx1)

 janssen 
PHARMACEUTICAL COMPANIES OF
Johnson & Johnson Replication Incompetent Adenovirus (Ad26)

 
SANOFI Adjuvanted protein subunit

 MERCK  iavi Replication-competent Vesicular Stomatitis Vector (VSV)

BARDA-Supported COVID-19 Vaccine Candidates

moderna

mRNA

AstraZeneca

Replication Incompetent Adenovirus (ChAdOx1)

janssen
PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

Replication Incompetent Adenovirus (Ad26)

SANOFI

Adjuvanted protein subunit

MERCK iavi

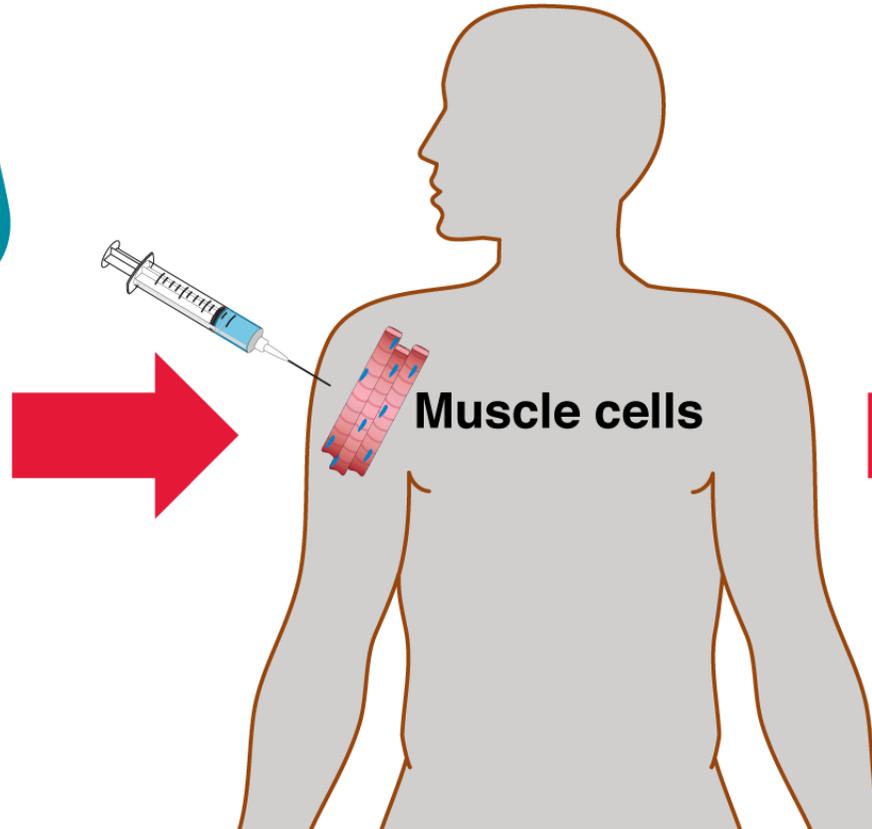
Replication-competent Vesicular Stomatitis Vector (VSV)

mRNA Vaccine Approach

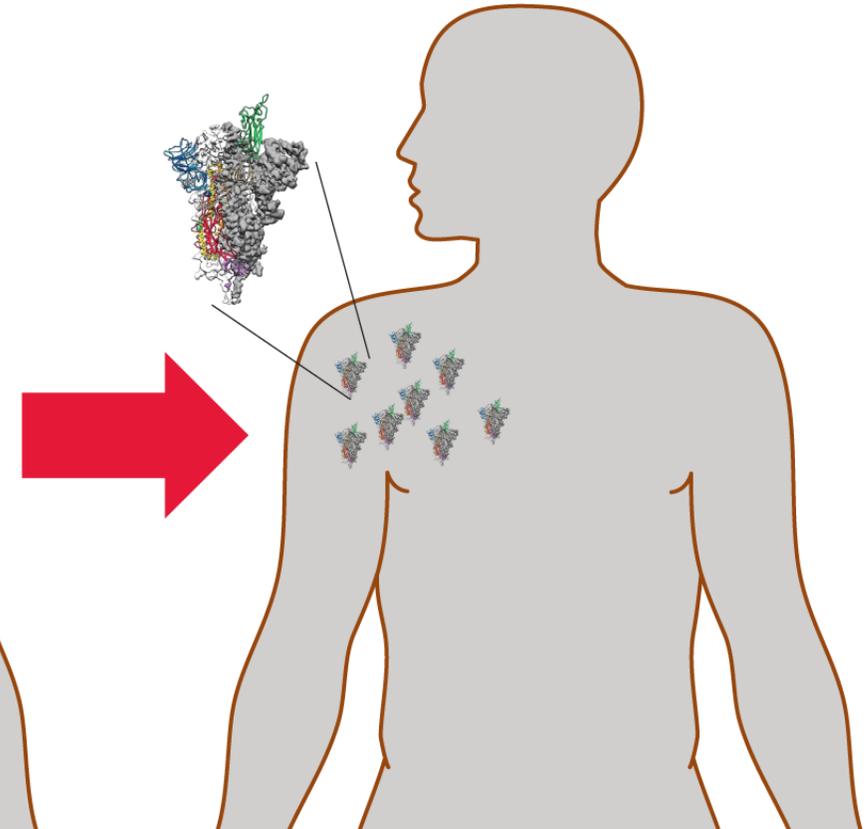
mRNA for spike protein of coronavirus



Inject into muscle cells



Muscle cells read the mRNA and make spike protein





News Release

NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins

Study Enrolling Seattle-Based Healthy Adult Volunteers

- **Trial of vaccine candidate mRNA-1273 will enroll 45 healthy adult volunteers ages 18 to 55 years over approximately 6 weeks**



The New York Times

May 18, 2020

Moderna Coronavirus Vaccine Trial Shows Promising Early Results

Data from 8 healthy volunteers: vaccine safe and provoked a strong immune response. It is on an accelerated timetable to begin larger human trials soon.



Health and Human Services

Press Release

May 15, 2020

Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'

- **National program to accelerate development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics**
- **Public-private partnership between HHS (CDC, FDA, NIH, BARDA), DoD, other federal agencies, and private firms**
- **Chief Scientific Advisor: Moncef Slaoui, PhD**
- **Chief Operating Officer: General Gustave F. Perna**

Published online May 11, 2020

Science

A Strategic Approach to COVID-19 Vaccine R&D

L Corey, JR Mascola, AS Fauci & FS Collins

- **Unprecedented collaboration and resources will be required to research and develop safe and effective vaccines for COVID-19 that can be manufactured and delivered in the scale of billions of doses to people globally.**

April 17: NIH Launches Public-Private Partnership to Speed COVID-19 Vaccine and Treatment Options

- **The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership will:**
 - **Standardize and share preclinical evaluation methods in an open forum**
 - **Prioritize and accelerate clinical evaluation of therapeutic candidates with near-term potential**
 - **Maximize clinical trial capacity and effectiveness**
 - **Advance vaccine development**

Briefing President Trump on the COVID-19 (Coronavirus) Outbreak



May 5: White House Briefing of Vice President Pence on COVID-19 Vaccines



January 29: White House Coronavirus Task Force Announced

Chair: VP Mike Pence

Response Coordinator: Deborah Birx

- Jerome Adams
- Alex Azar
- Stephen Biegun
- Robert Blair
- Ben Carson
- Francis Collins
- Ken Cuccinelli
- Kelvin Droegemeier
- Thomas Engels
- Anthony Fauci
- Joe Grogan

- Stephen Hahn
- Derek Kan
- Larry Kudlow
- Chris Liddell
- Steven Mnuchin
- Robert O'Brien
- Sonny Perdue
- Matthew Pottinger
- Robert Redfield
- Gene Scalia
- Joel Szabat



- Seema Verma
- Robert Wilkie