

Update on COVID-19 for NIAID HIV/AIDS Community Advisory Boards

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National Institutes of Health

June 10, 2020



1

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

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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



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3



Centers for Disease Control and Prevention

Press Release

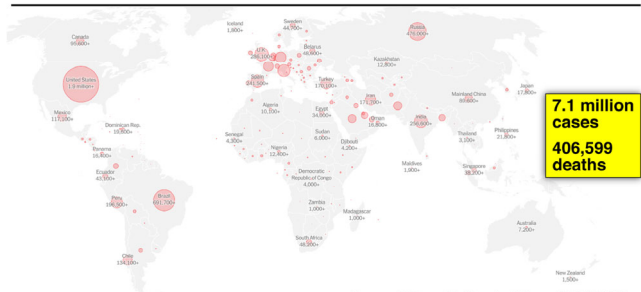
January 21, 2020

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

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4

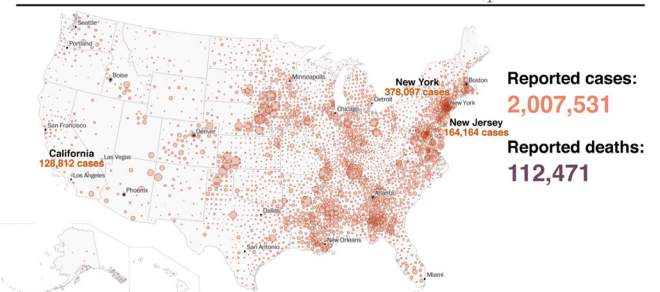
COVID-19 Globally: 7.1 Million Cases in 213 Countries and Territories



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5

Reported COVID-19 Cases and Deaths in the United States



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6

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

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7

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8

Basic Research, Pathogenesis, Animal Models, Epidemiology

- Basic research on viral biology, life cycle, pathogenesis, and transmission
- Large-scale natural history, serosurveillance and immunophenotyping studies
 - Identify predictors of disease progression
 - Characterize disease progression and antibody response
 - Characterize transmission, particularly the roles of asymptomatic transmission and children
- Set up animal model testing for therapeutics and vaccines
- Source research reagents and make them available to the research community

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9

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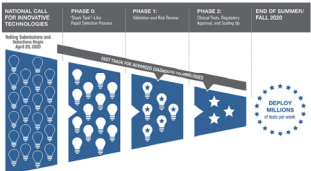
10

NIH National Institutes of Health
Turning Discovery Into Health
Wednesday, April 29, 2020

News Release

NIH Mobilizes National Innovation Initiative for COVID-19

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



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11

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12

Investigational Therapeutics for COVID-19

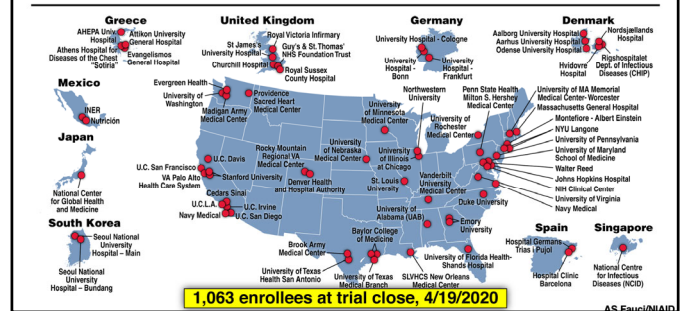
- Remdesivir
- Other broad-spectrum antivirals
- Convalescent plasma/hyperimmune immunoglobulin
- Repurposed drugs, e.g. hydroxychloroquine, lopinavir/ritonavir
- Host modifiers/immune-based therapies
- Anti-SARS-CoV-2 monoclonal antibodies
- Others



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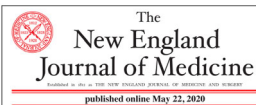
13

NIAID Adaptive Randomized, Controlled Treatment Trial for COVID-19



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14



Remdesivir for the Treatment of Covid-19 – Preliminary Report

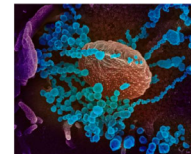
J.H. Beigel, H.C. Lane et al. for the ACTT-1 Study Group Members

- 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

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15

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



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16



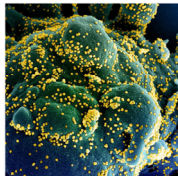
Tuesday, April 21, 2020

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)

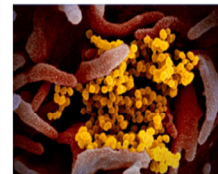


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17

NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

APRIL 10, 2020

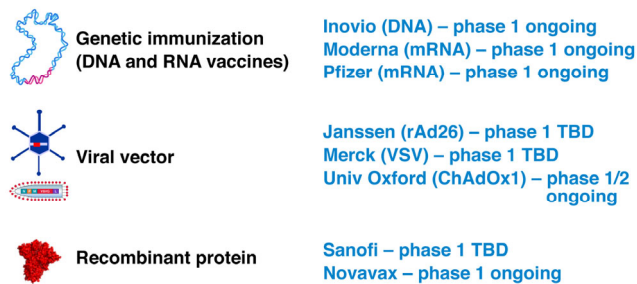


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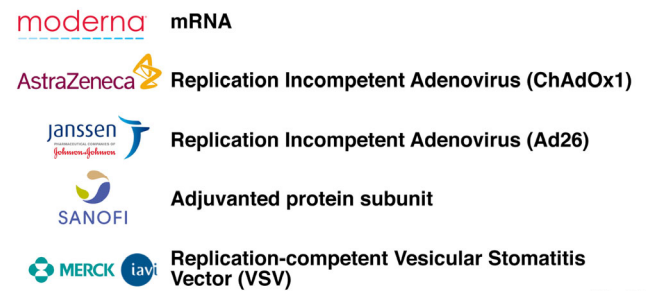
18

Vaccine Platform Technologies



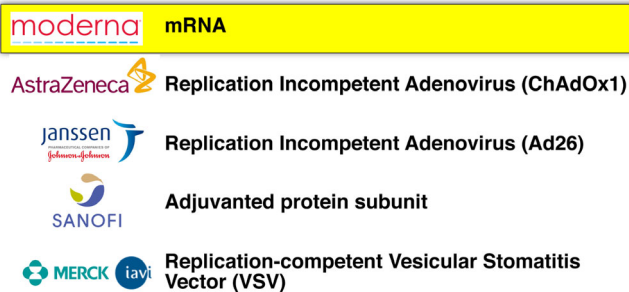
19

BARDA-Supported COVID-19 Vaccine Candidates



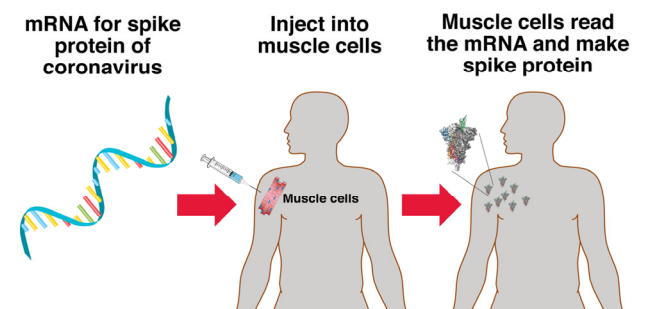
20

BARDA-Supported COVID-19 Vaccine Candidates



21

mRNA Vaccine Approach



22

NIH National Institute of Allergy and Infectious Diseases

News Release

March 16, 2020

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

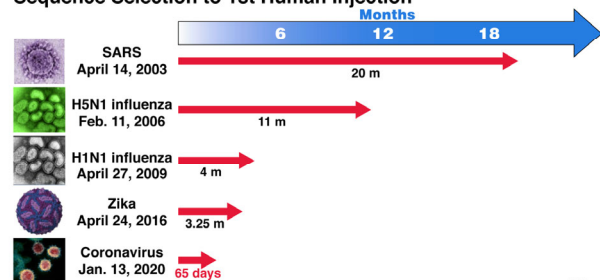


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23

NIH Vaccine Research Center: Vaccines for Emerging Diseases

Sequence Selection to 1st Human Injection



24

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.

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25

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.

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26

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 components of HHS (CDC, FDA, NIH, BARDA); Department of Defense; other federal agencies; and private firms
- Chief Scientific Advisor: Moncef Slaoui, Ph.D.
- Chief Operating Officer: General Gustave F. Perna

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27

NIH National Institutes of Health
Turning Discovery Into Health
Friday, April 17, 2020

News Release

NIH to Launch 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

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28

The NIAID CoV Prevention Network (CoVPN)

- The CoVPN combines expertise from 3 networks supported by DAIDS and DMID and their global partners
 - HVTN, HPTN and Infectious Diseases Clinical Research Consortium (IDCRC)
 - Serve as focal point for USG-sponsored trials of COVID-19 vaccines and mAbs for preventing acquisition of SARS-CoV-2 and reduce medical and economic consequences of COVID-19
- Networks will continue priority projects in HIV prevention (HVTN and HPTN) and non-COVID vaccine work (IDCRC)

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29

The NIAID CoV Prevention Network (CoVPN)

Candidate COVID-19 vaccines

Platform 1	Platform 2	Platform 3	Platform 4	Platform 5
Harmonized efficacy trials	Collaborating clinical trials networks	Collaborating labs 1) Defining COVID infections from vaccination 2) Quantitative immune responses to spike and spike epitopes 3) T-cell responses	Data and Safety Monitoring Board	Between-trial statistical group for correlates of protection

NIH/COVID Network-supported infrastructure

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30

COVID-19 and Persons with HIV (PWH)

- Unknown if PWH have an increased incidence of infection with SARS-CoV-2
- Large study testing PWH for SARS-CoV-2 found no difference in incidence related to CD4+ T cell count, viral load or antiretroviral drug regimen
- PWH with co-morbidities are more vulnerable to complications of COVID-19 similar to general population with co-morbidities
- Complications of COVID-19 occur at younger age in PWH compared to general population (? HIV premature aging phenomenon)
- The same minority groups who have disproportionate incidence of HIV have a disproportionate incidence of severe COVID-19 disease

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31

January 29: White House Coronavirus Task Force Announced

Chair: VP Mike Pence

Response Coordinator: Deborah Birx

- | | |
|----------------------|---------------------|
| ■ Jerome Adams | ■ Stephen Hahn |
| ■ Alex Azar | ■ Derek Kan |
| ■ Stephen Biegun | ■ Larry Kudlow |
| ■ Robert Blair | ■ Chris Liddell |
| ■ Ben Carson | ■ Steven Mnuchin |
| ■ Francis Collins | ■ Robert O'Brien |
| ■ Ken Cuccinelli | ■ Sonny Perdue |
| ■ Kelvin Droegemeier | ■ Matthew Pottinger |
| ■ Thomas Engels | ■ Robert Redfield |
| ■ Anthony Fauci | ■ Gene Scalia |
| ■ Joe Grogan | ■ Joel Szabat |



- Seema Verma
- Robert Wilkie

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32

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



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33



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34

Questions?

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35