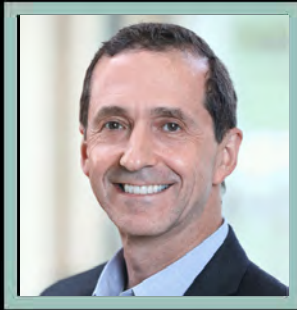
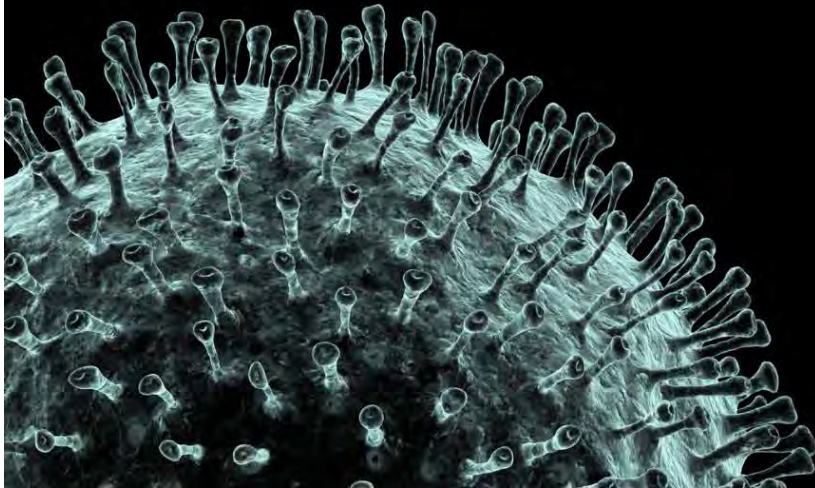


COVID-19 Conversations



John R. Mascola

Director, Dale and Betty Bumpers Vaccine
Research Center, National Institute of Allergy
and Infectious Diseases



[COVID19Conversations.org](https://www.covid19conversations.org)

#COVID19Conversations



AMERICAN PUBLIC HEALTH ASSOCIATION
For science. For action. For health.



June 10, 2020

John R. Mascola, M.D.
Director, Vaccine Research Center
National Institute of Allergy and Infectious
Diseases, NIH



Dale and Betty Bumpers
VACCINE RESEARCH CENTER
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Department of Health and Human Services



National Institute of
Allergy and
Infectious Diseases

SARS-CoV-2 spike protein is vaccine target

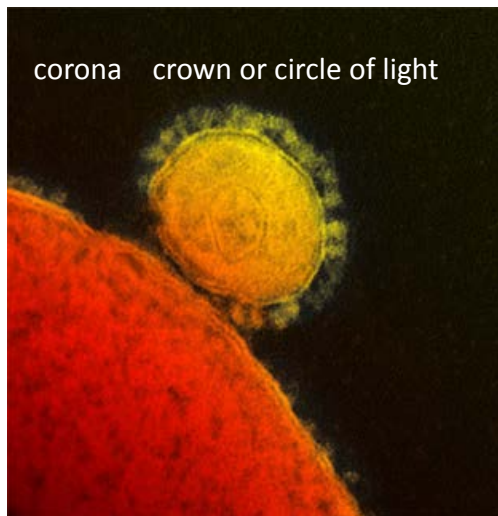
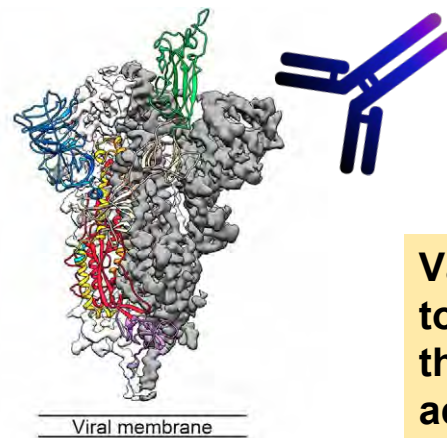


Image of SARS-CoV-2 virus attached to host cell



Spike Protein

Model rendering of Coronavirus Spike Protein – Allows researchers to find unique binding areas to target for vaccine development

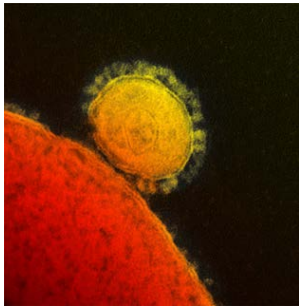


Antibodies against virus

Vaccines teach the immune system to make antibodies that can block the virus from infecting cells - and activate other immune responses to fight viral infection

Wrapp D, Wang N, Corbett KS, Goldsmith JA, Hsieh CL, Abiona O, Graham BS, McLellan JS. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. Science. 2020 Feb 19:eabb2507.

COVID-19: Examples of Types of Vaccines



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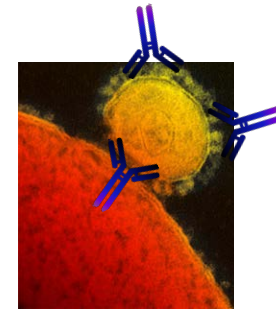


Protein vaccine injected into muscle

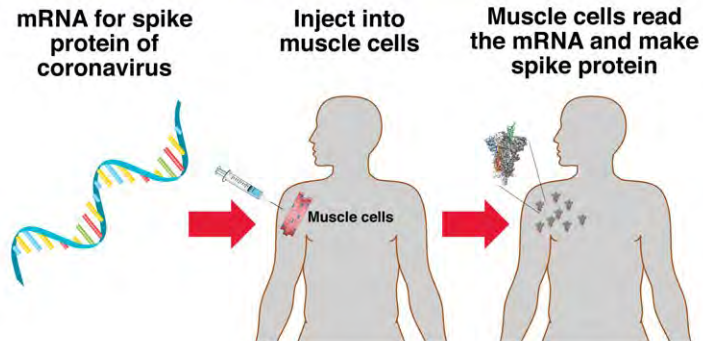


RNA vaccine injected in muscle

Immune system generates antibodies to block viral infection



mRNA is the genetic backbone that encodes for the spike protein for SARS-CoV-2



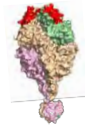
Examples of COVID-19 Candidate Vaccines

Type of vaccine approach

Vaccine companies

Protein Sub-Unit

Ex: Hepatitis B, Influenza

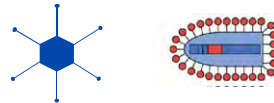


Genetic (DNA, mRNA)



Viral Vectors

Ex: ERVEBO Ebola vaccine manufactured by Merck



April 17: NIH Launches Public-Private Partnership – Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

INDUSTRY LEADERS



GOVERNMENT LEADERS



NON-PROFIT/ PROGRAM MANAGEMENT





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

The full development pathway for an effective vaccine for SARS-CoV2 will require that industry, government, and academia collaborate in unprecedented ways, each adding their individual strengths. . . .We further discuss a collaborative platform for conducting harmonized, randomized controlled vaccine efficacy trials. This mechanism aims to generate essential safety and efficacy data for several candidate vaccines in parallel, so as to accelerate the licensure and distribution of multiple vaccine platforms and vaccines to protect against COVID-19

Harmonized Phase 3 Trials

Candidate COVID-19 vaccines

Platform 1

Platform 2

Platform 3

Platform 4

Platform 5

Harmonized efficacy trials

Collaborating clinical trials networks

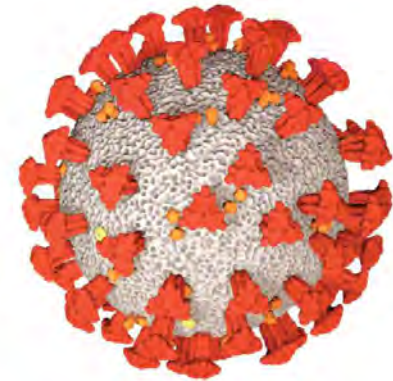
Collaborating labs

- 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



COVID-19
Prevention Network

COVID-19 Vaccine Development Process

- Phase 3 trials of several types of vaccines to test if vaccine can prevent COVID-19 disease**
- In parallel, scale up and manufacture vaccines, so there is no gap between information above, and availability of vaccine**
- In U.S., the FDA would review clinical data, and decide if vaccine should be licensed for use**
- CDC would make recommendations for who should get vaccine**