



# THE COVID-19 VACCINE: THE FACTS AND THE WAY FORWARD

December 15, 2020

# Welcome!



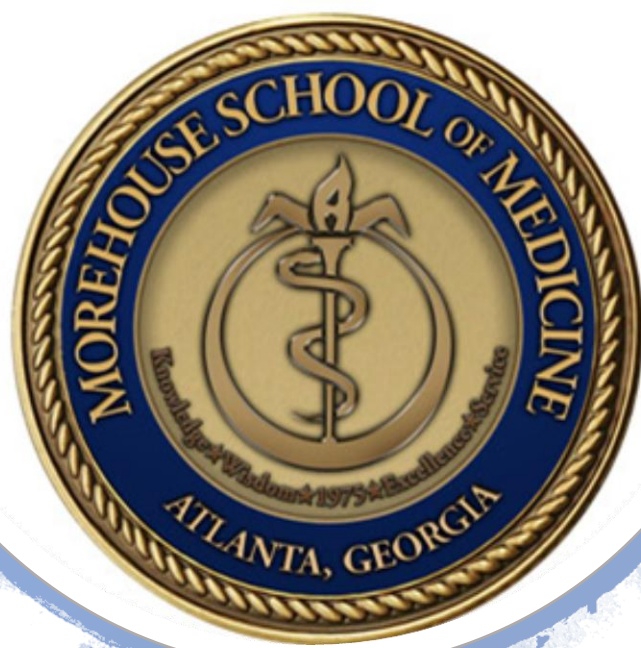


# THE FACTS

# **DR. LILLY IMMERGLUCK**

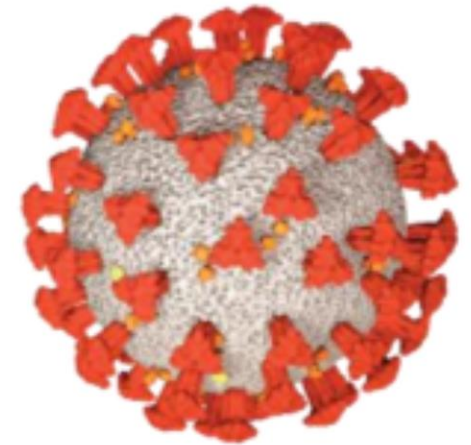
**Principal Investigator, US COVID-19 Prevention Network  
Site for Morehouse School of Medicine**





December 15, 2020

# Morehouse School of Medicine's CoVID-19 Vaccine Trials



**COVID-19**  
Prevention Network

# OBJECTIVES

- How Does a Vaccine Work?
- Process in Vaccine Development → Licensure
  - ‘Emergency Use Authorization Approval’ vs. ‘Standard Approval’
- Estimated Timelines for Distribution
- How to Determine Vaccine Efficacy?

# Goal of COVID Vaccine Trials...

***“Having a safe and effective medical countermeasure to prevent COVID-19 would enable us to not only save lives but also help end the global pandemic.***

*Centralizing our clinical research efforts into a single trials network will expand the resources and expertise needed to efficiently identify safe and effective vaccines and other prevention strategies against COVID-19”*

**-- Anthony S. Fauci, M.D.  
NIH-NIAID Director**

# COVID-19 PREVENTION NETWORK

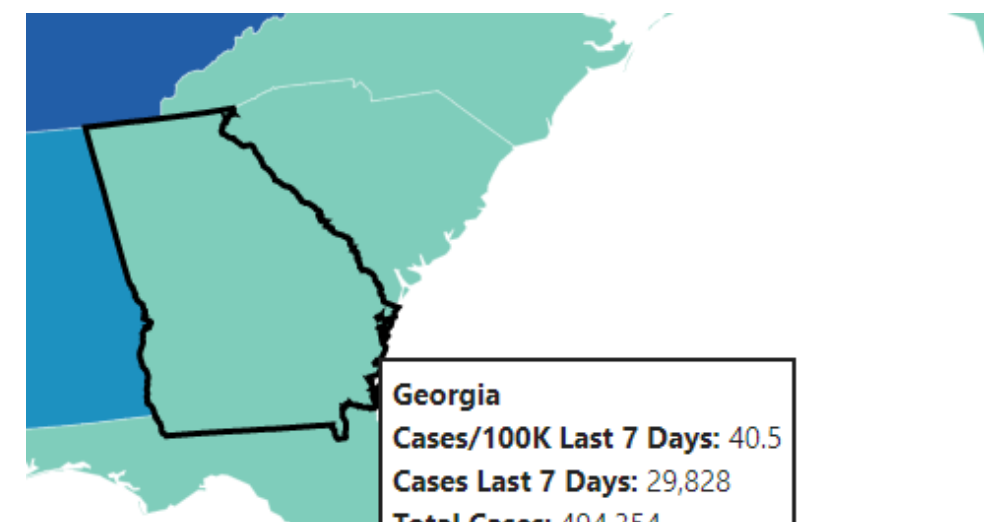
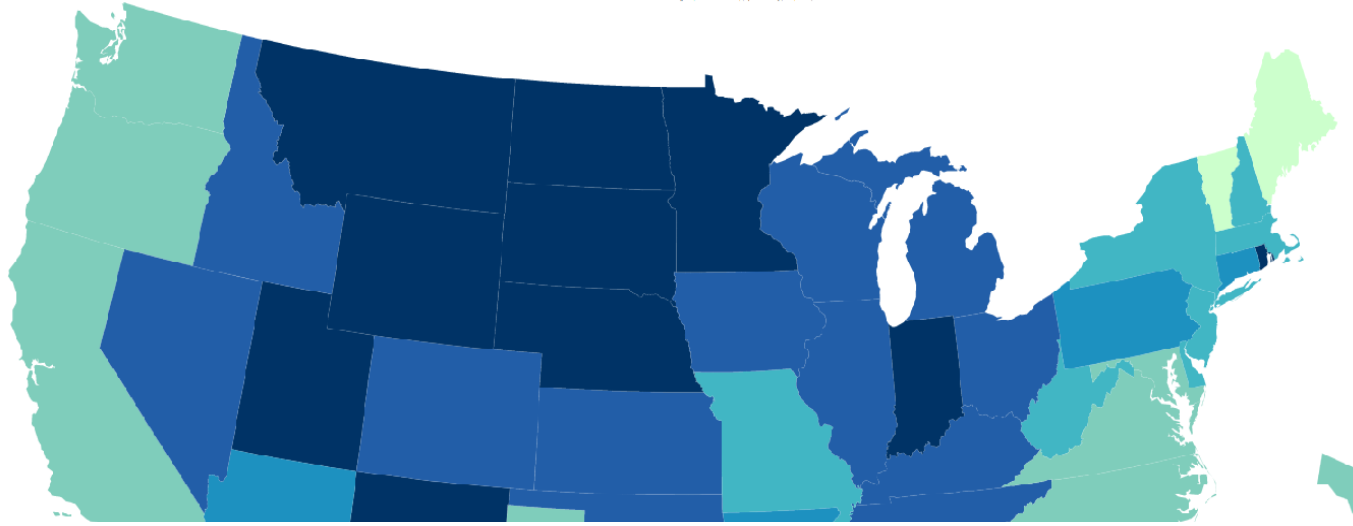
- **COVID-19 Prevention Trials Network (COVPN)** was established by merging four existing **NIAID-funded clinical trials networks**:
  - HIV Vaccine Trials Network (HVTN), based in Seattle;
  - HIV Prevention Trials Network (HPTN), based in Durham, N.C.;
  - Infectious Diseases Clinical Research Consortium (IDCRC), based in Atlanta;
  - AIDS Clinical Trials Group, based in Los Angeles.
- **COVPN** will use a **harmonized vaccine protocol** developed by the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) **public-private partnership**.
  - Enable analyses of correlates of protection across multiple vaccine trials.
  - >100 clinical trial sites across the United States and internationally.





# Why it is important to be a part of US CoVID-19 Prevention Network?

*Why should people of color participate in these vaccine clinical trials?*



Reported to the CDC since January 21, 2020

TOTAL CASES  
**16,113,148**  
 +181,032 New Cases

AVERAGE DAILY CASES PER 100K IN LAST 7  
 DAYS  
**64.5**

TOTAL DEATHS  
**298,266**  
 +1,448 New Deaths

CDC | Updated: Dec 14 2020 12:16PM

**Average Daily Cases per 100,000 in Last 7 Days**



# CoVID-19 Statistics

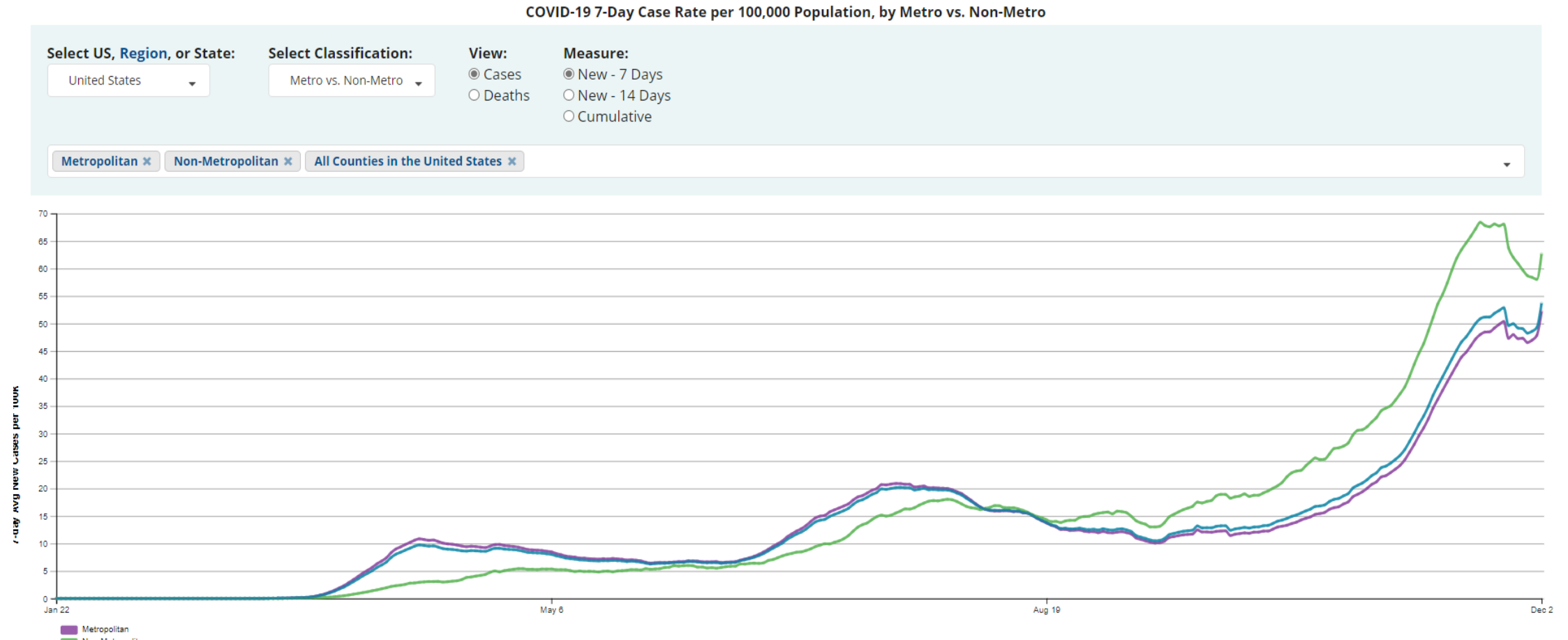
(Updated: December 5, 2020)

[Accessed: CDC COVID Data Tracker](#)



# CoVID-19 Seven Day Case Rate per 100,000 Population

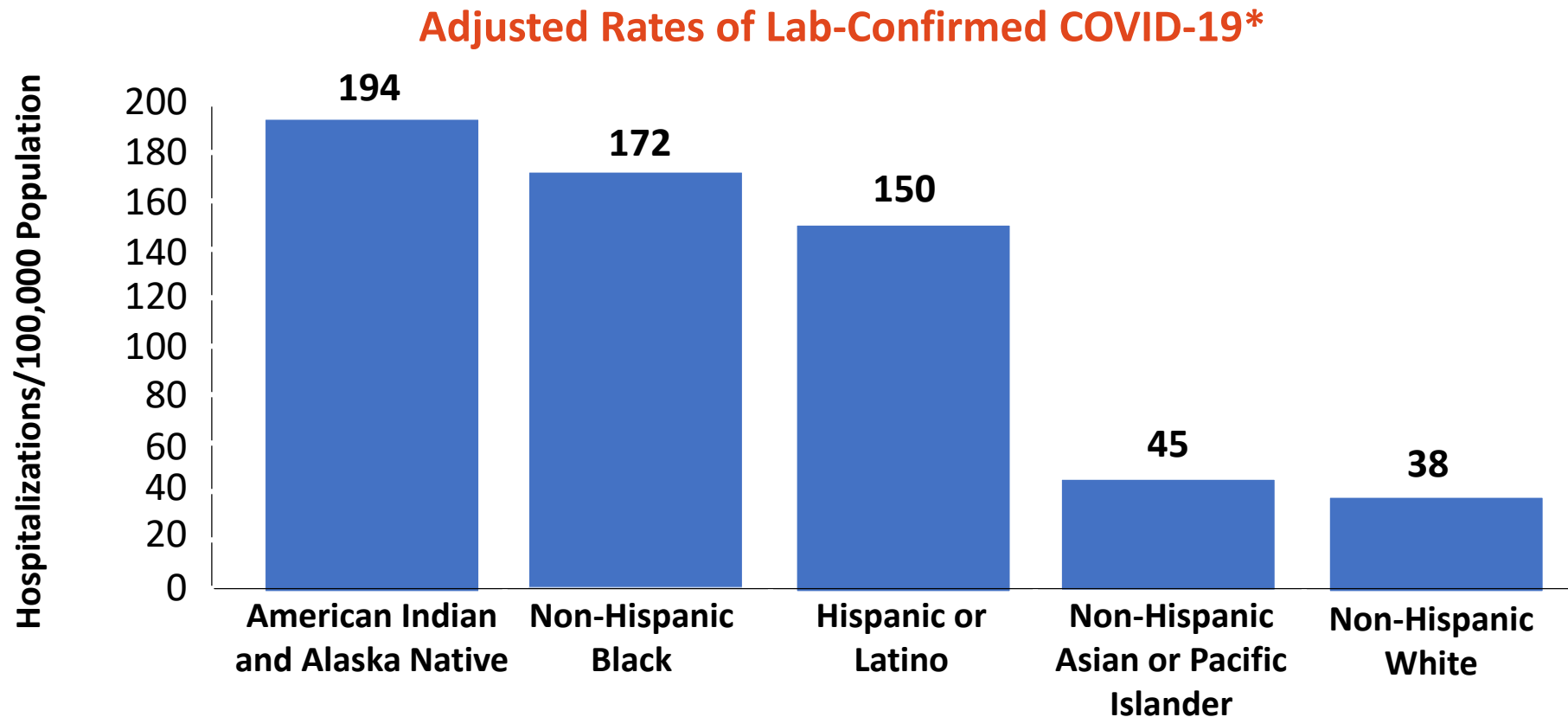
January 22, 2020 – December 2, 2020



# Grim Facts....(as of 12/2/2020)

- On **December 2**--Single day hit a record in the U.S. as hospitalizations surpassed 100,000 for the first time this past week, leaving hospitals in some regions of the country **without enough beds** in intensive-care units to meet their patients' needs.
- U.S. recorded **2,804** deaths on Wednesday (12/2/2020)
- **Every 33 seconds**, someone is dying from CoVID-19 (12/5/2020)
- **Number 1 cause of death** in the US (surpassing deaths from cancer and cardiovascular diseases).

# COVID-NET: COVID-19–Associated Hospitalization By Race and Ethnicity



\*Data from March 1, 2020 – June 6, 2020 covers ~ 10% of US population: 99 counties in 14 states (CA, CO, CT, GA, IA, MD, MI, MN, NM, NY, OH, OR, TN, UT). Adjusted to account for differences in age distribution within race and ethnicity groups.

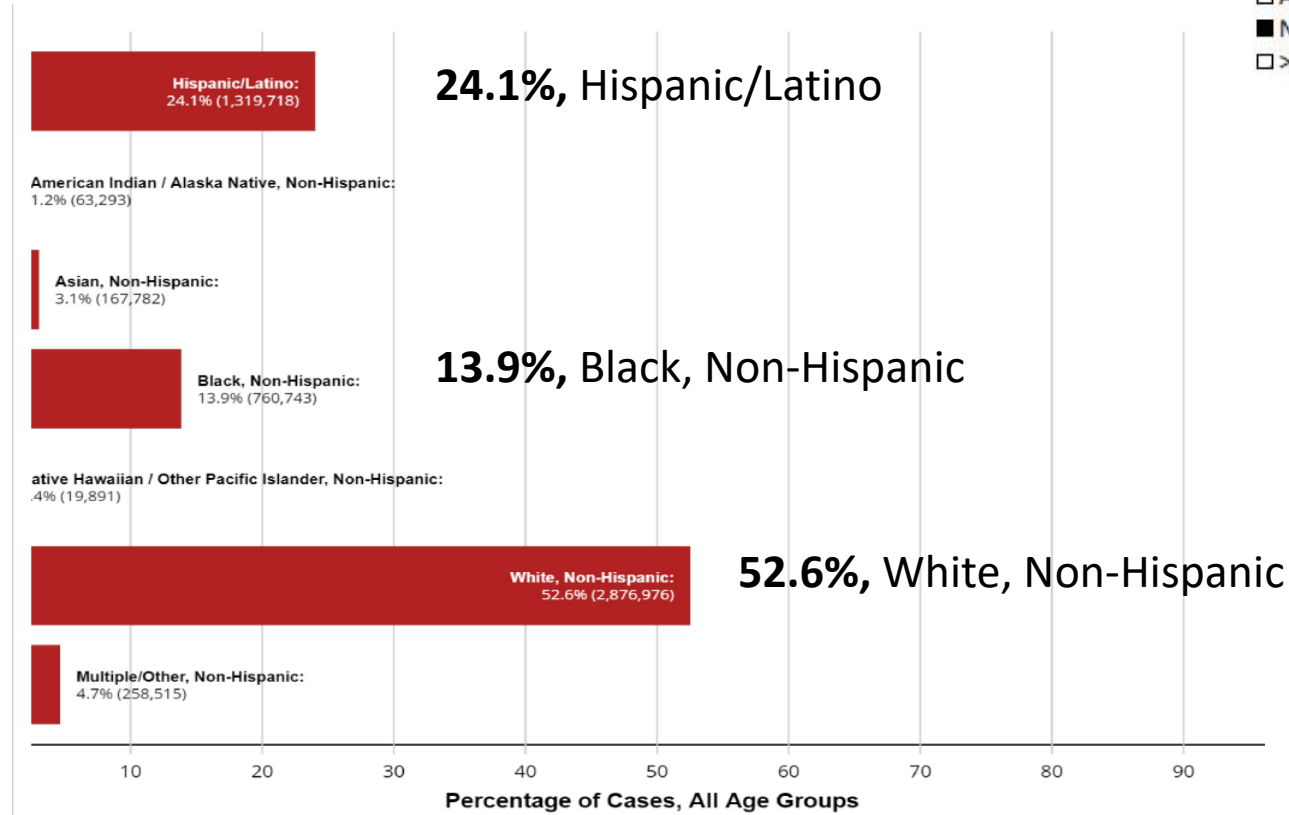
<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/data-visualization.htm>

Slide credit: [clinicaloptions.com](https://clinicaloptions.com)

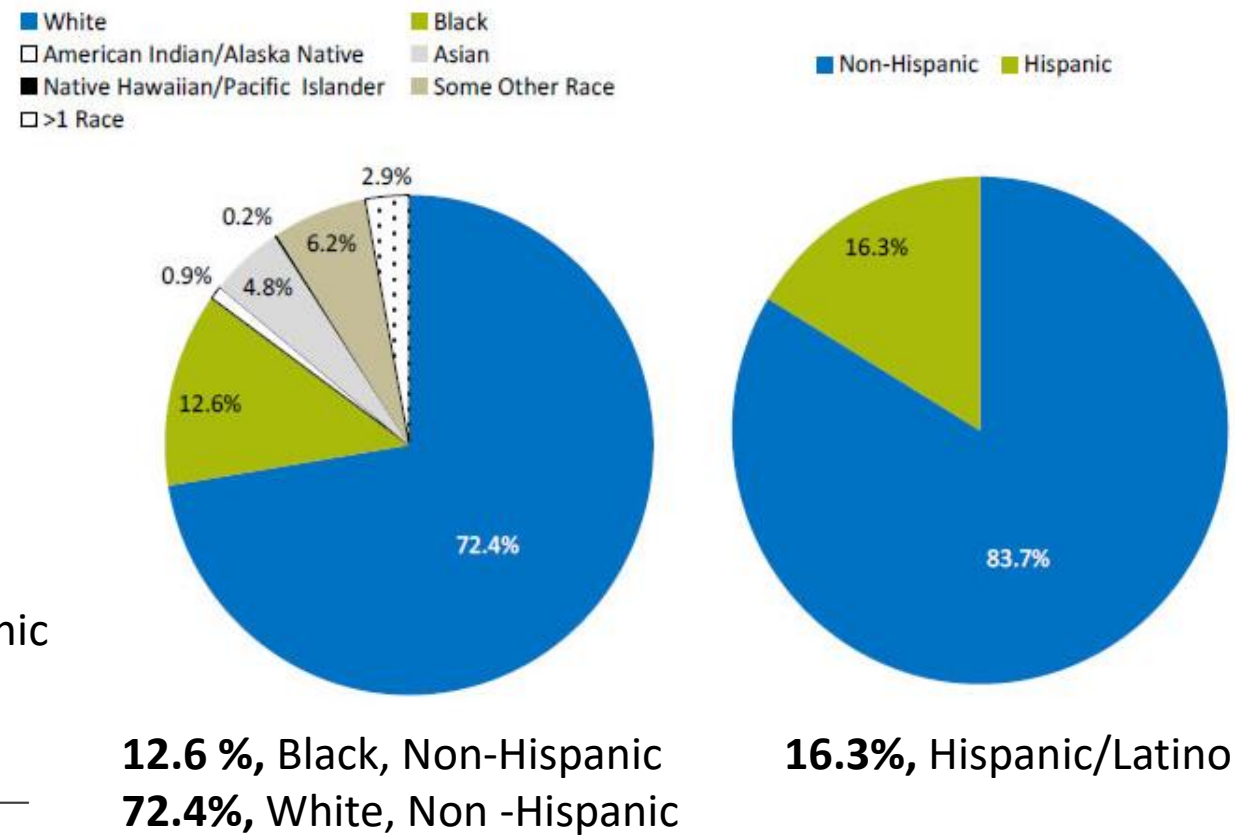


# Race/Ethnicity– Impact from CoVID-19 Infections

Rate of Confirmed CoVID-19 Cases US  
(12/5/2020)

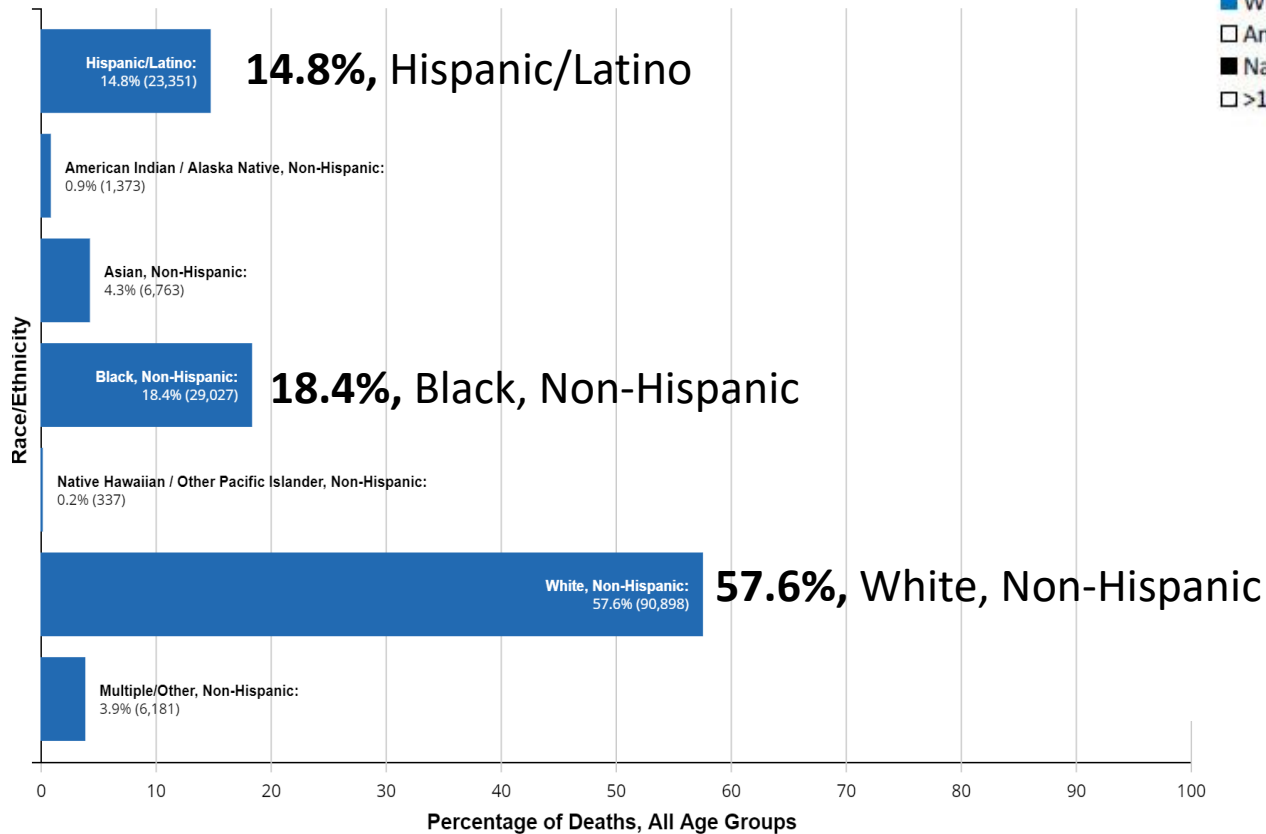


Race/Ethnicity, US Population

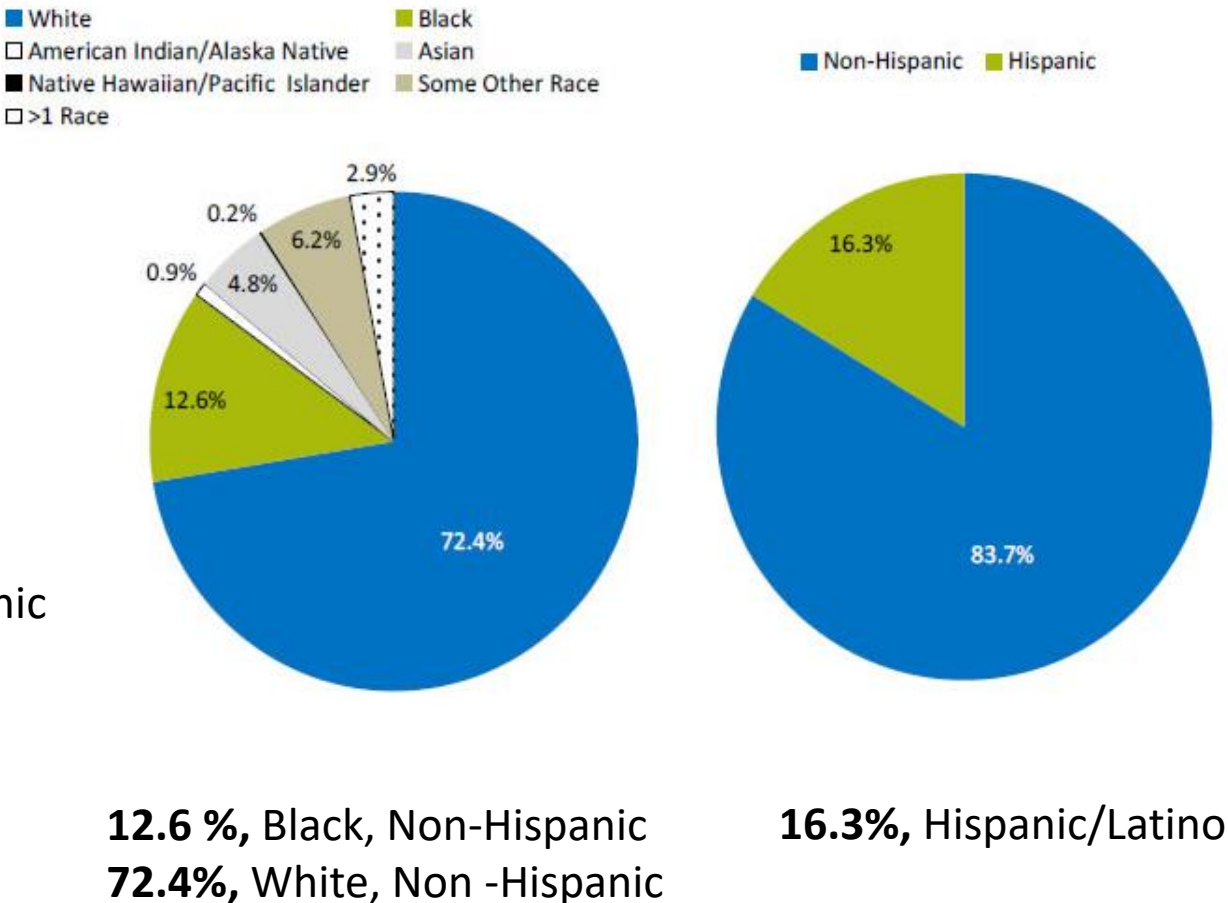


# Race/Ethnicity– Impact from CoVID-19 Deaths

CoVID-19 DEATHS in US (12/5/2020)



Race/Ethnicity, US Population



# What do we need to know about CoVID-19 vaccine trials

[Addressing 9 COVID-19 Myths and Facts - YouTube](#)

# What We Need to Know about Vaccines

‘Vaccine 101’

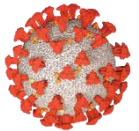
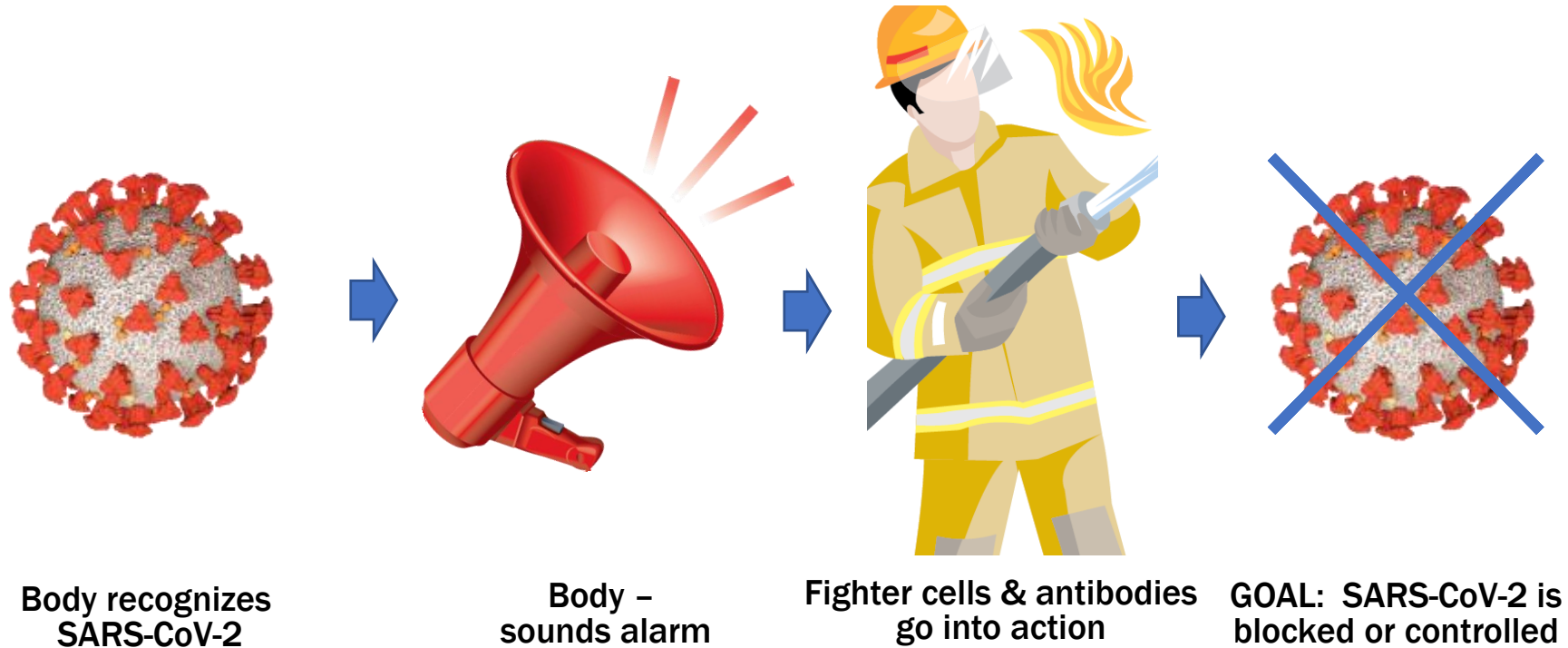
# How do vaccines work?

- Mimics the infectious bacteria or viruses that cause disease.
- Stimulates the body's immune system to build up defenses against the infectious bacteria or virus (organism) without causing the disease.
  - The parts of the infectious organism that the immune system recognizes are foreign to the body and are called **antigens**.
  - Vaccination exposes the body to these antigens.



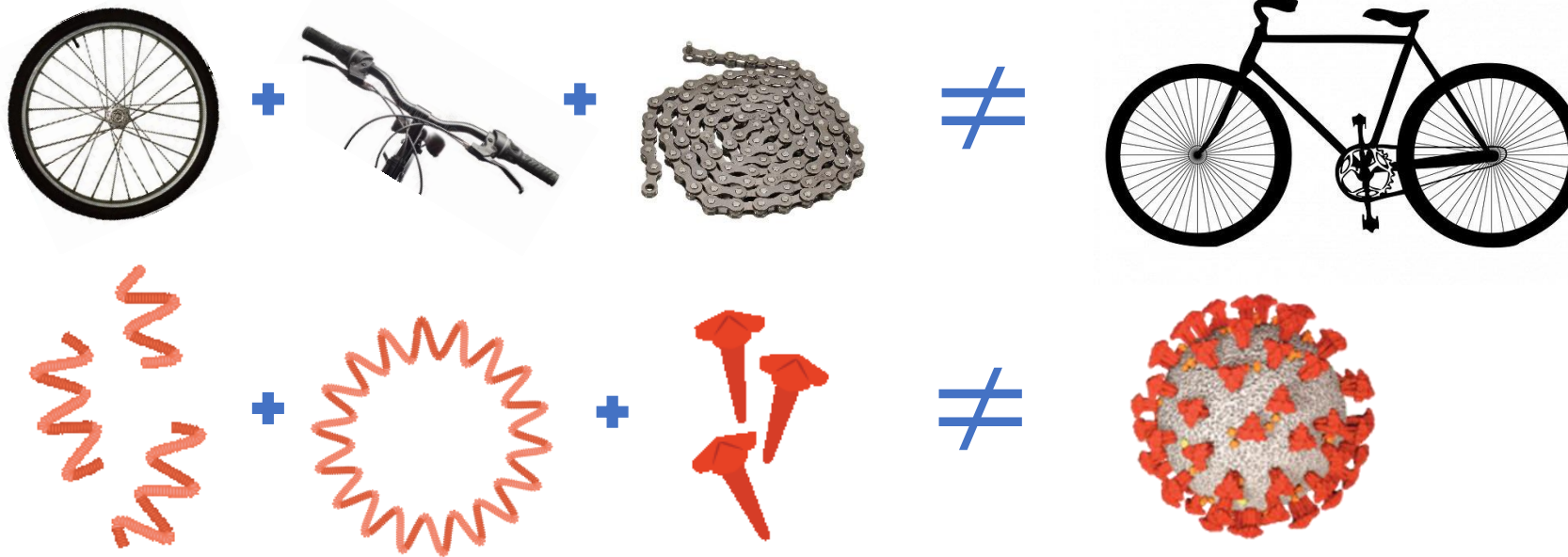
# How does a vaccine work?

By teaching the body to recognize and fight invaders



# Can vaccines cause SARS-CoV-2 infection or cause COVID-19 illness?

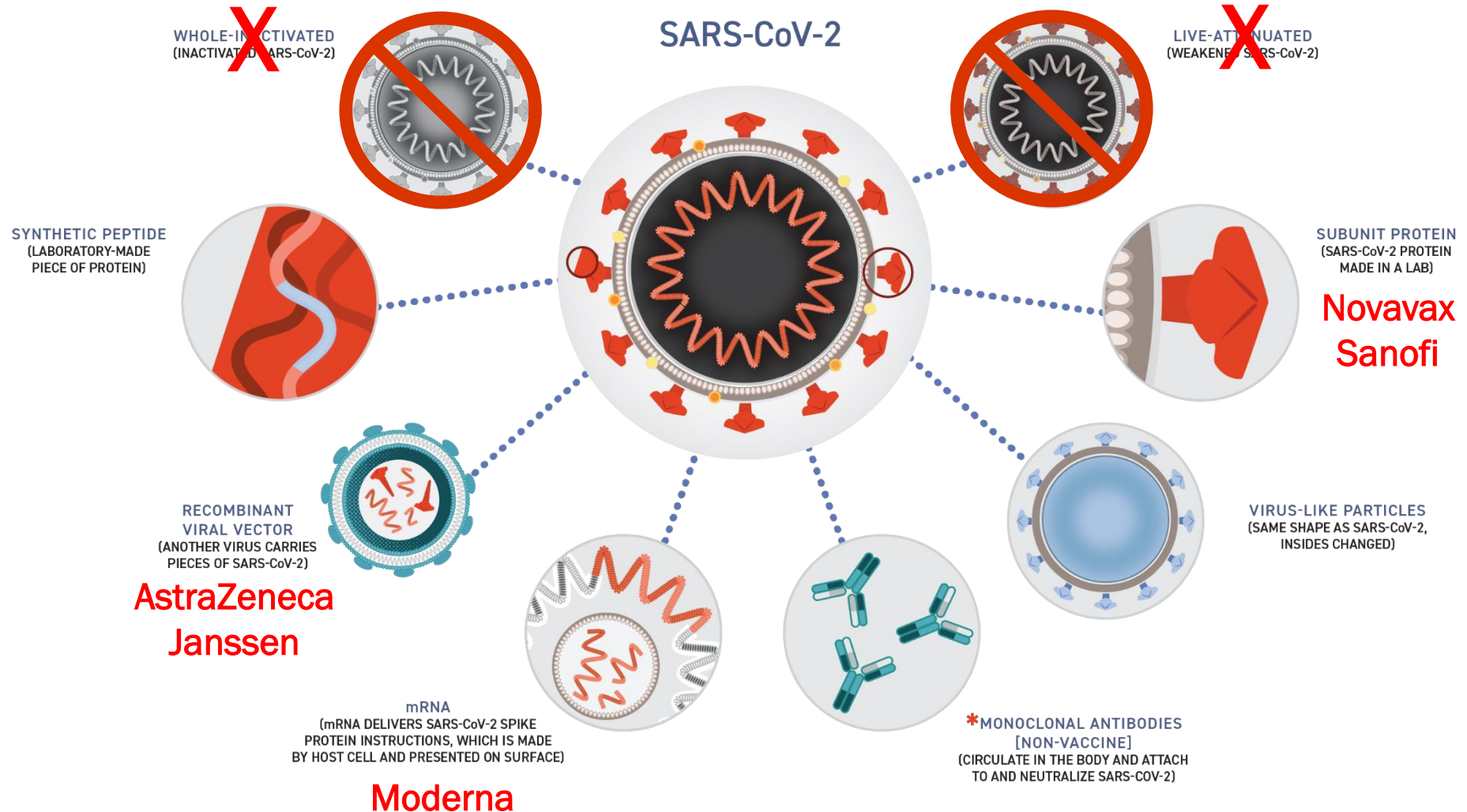
**NO!** The vaccines being tested are made from synthetic (laboratory made) pieces copied from SARS-CoV-2, not the whole virus. Therefore, the vaccines CANNOT cause infection or cause you to get COVID-19 illness.



*Image Credit: Bridge HIV/SFDPH*

# Vaccine Designs

## SARS-CoV-2 VACCINE AND RELATED\* DESIGNS



# Two Different Types of CoVID-19 Vaccine Candidates:

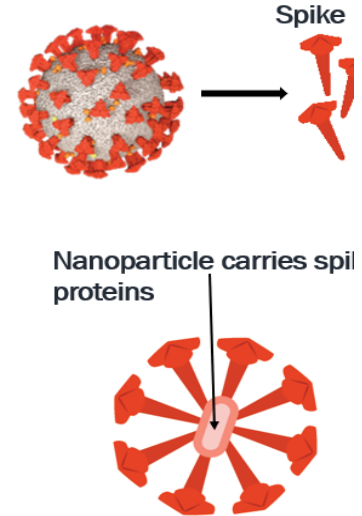
Both Use 'Spike'  
Protein to  
generate immune  
response

## The protein subunit vaccine approach

Novavax re-creates the "spike" protein of the SARS-CoV-2 virus in the laboratory. These proteins are called the **antigen**, which is the vaccine ingredient that causes an immune response.

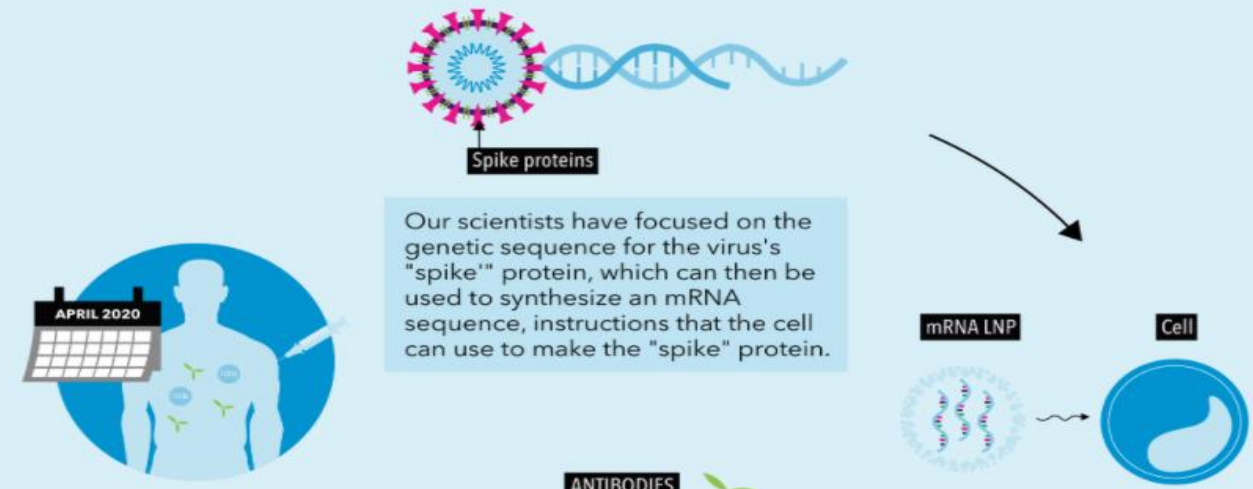
The antigen is delivered on a "nanoparticle" (a microscopic particle).

The same nanoparticle design was used in a Phase 3 study for a flu vaccine for older adults called NanoFlu, which is now in preparation to file for licensure by the FDA.



## UNDERSTANDING mRNA VACCINES

To build an mRNA vaccine, scientists only need access to the genetic sequence of SARS-CoV-2, and not the actual virus.



# Vaccine Development Process

Standard Process



# PHASES OF A VACCINE CLINICAL TRIAL

## Pre-clinical: (Years)

Research laboratory in a university, medical center or small biotech company

- several different scientists or groups of scientists may be working toward developing a vaccine against a GERM (virus or bacteria)

## Phase I: (1-2 Years) TEST in small number of **healthy adults**.

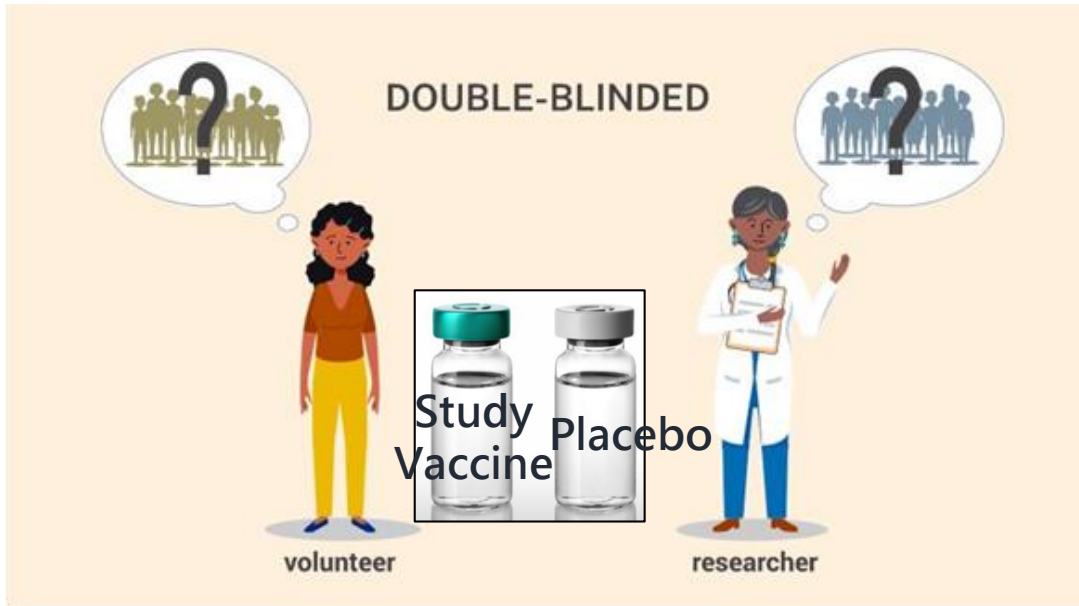
- These placebo-controlled studies usually include less than 100 people
- Answer two main questions:
  - does the vaccine generate the expected immune response and
  - is the vaccine safe?

## Phase II: (2 years+)

Several hundred people, comparing those who did and did not receive vaccine

- **proper dose** of vaccine to be given,
- continue to study the **vaccine's safety**
- **methods for manufacturing** the vaccine,

# Phase III Vaccine Development: (3-4 years)



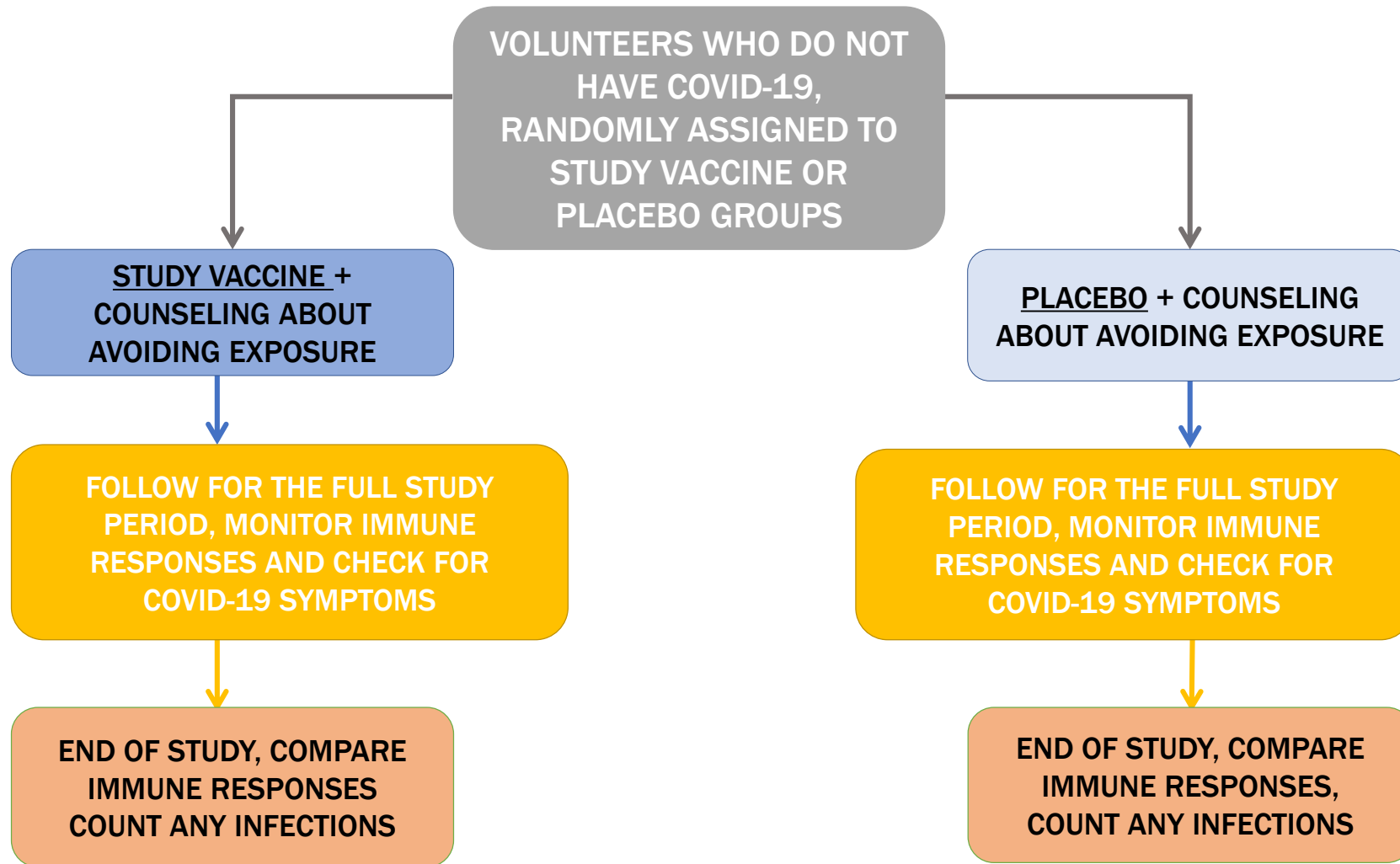
**Randomized, Blinded, Control Trial** → 'Flipping a Coin'

**Placebo**-sterile salt water with NO vaccine ingredients  
**Study Vaccine**- vaccine ingredients but only unblinded pharmacy knows.

1:1 or 1:2 ratio of Placebo: Study Vaccine:

- **Thousands** of study participants who are similar to the population that will receive the vaccine
  - final stage of development before a company requests product licensing
  - **Number of Participants is calculated** so that statistical differences between the experimental group and control group can be observed.
    - Frequency of disease in the population
- **Monitoring of Any testing sites** (those recruiting patients or testing samples) to ensure that protocols are being followed consistently.
  - Samples must be collected and analyzed
    - ***Immune responses***
    - ***Disease***
    - ***Adverse reactions***

# All Participants Receive the Best Risk Reduction Education Available



# Phase IV (Post-Licensure):

- **Experts for CDC** will also review the data and determine who should be able to get the vaccine.
- **Company or healthcare providers** who helped run the Phase III studies will also publish the results in a scientific journal for review by other scientists.
- **Additional studies:** Because some rare side effects may not have been detected in the Phase III trials, vaccine safety is continually monitored by the CDC.
  - **Monitor Disease prevalence** after vaccine available to general population (Focus on areas high rates of disease and high rates of vaccine distribution)
  - VAERS- Vaccine Adverse Event Reported System (CDC +FDA monitor)

# What is the Advisory Committee on Immunization Practices (ACIP)

- Group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States.
- **15 experts** who are **voting** members and are responsible for making vaccine recommendations.
  - Expertise in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, or preventive medicine.
  - One member is a consumer representative who provides perspectives on the social and community aspects of vaccination.
- **30 nonvoting** representatives from professional organizations that are highly regarded in the health field.

# Function of ACIP- Usually meet 3 times a year\*

- All meetings are open to the public and available online via webcast.
  - Review findings and discuss vaccine research and scientific data related to vaccine effectiveness and safety, clinical trial results, and manufacturer's labeling or package insert information.
- Outbreaks of vaccine-preventable disease or changes in vaccine supply, such as vaccine shortages, also are reviewed during these meetings.
- Provide recommendations
  - Who should receive the vaccine,
  - How many doses needed,
  - How much time between doses
  - Determine precautions and contraindications

*\*during pandemic, ACIP has met more frequently*

# Data Safety Monitoring Board (DSMB)

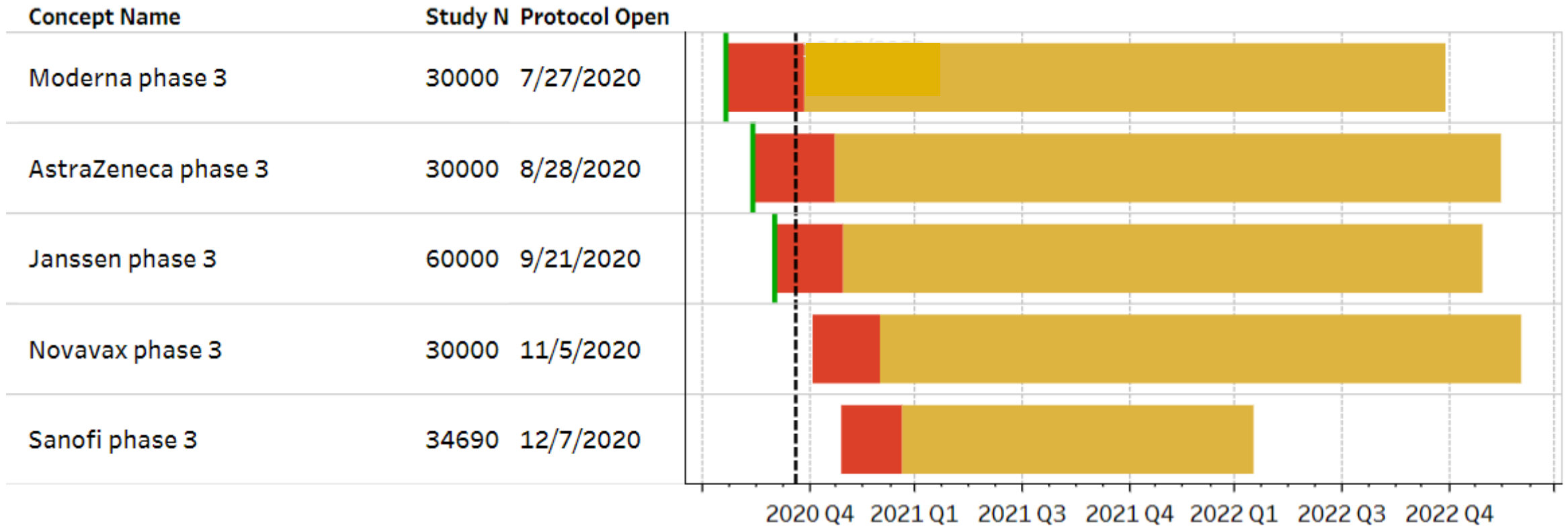
- A Data Safety Monitoring Board evaluates data from the **Phase 3** clinical trial and advises the vaccine manufacturer regarding whether criteria for the pre-specified clinical endpoint, as discussed and agreed to in advance with FDA, has been met for their COVID-19 vaccine.
- Independent Board



# Current State of the CoVID-19 Vaccine(s)

# Phase 3 Vaccine Pipeline

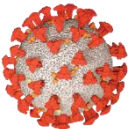
Study opening dates are projections, and subject to change.



**Pfizer, phase 3:** Pfizer did not accept federal funding to help develop or manufacture the vaccine, unlike front-runners Moderna and AstraZeneca. Company is part of Operation Warp Speed as a supplier of a potential coronavirus vaccine.

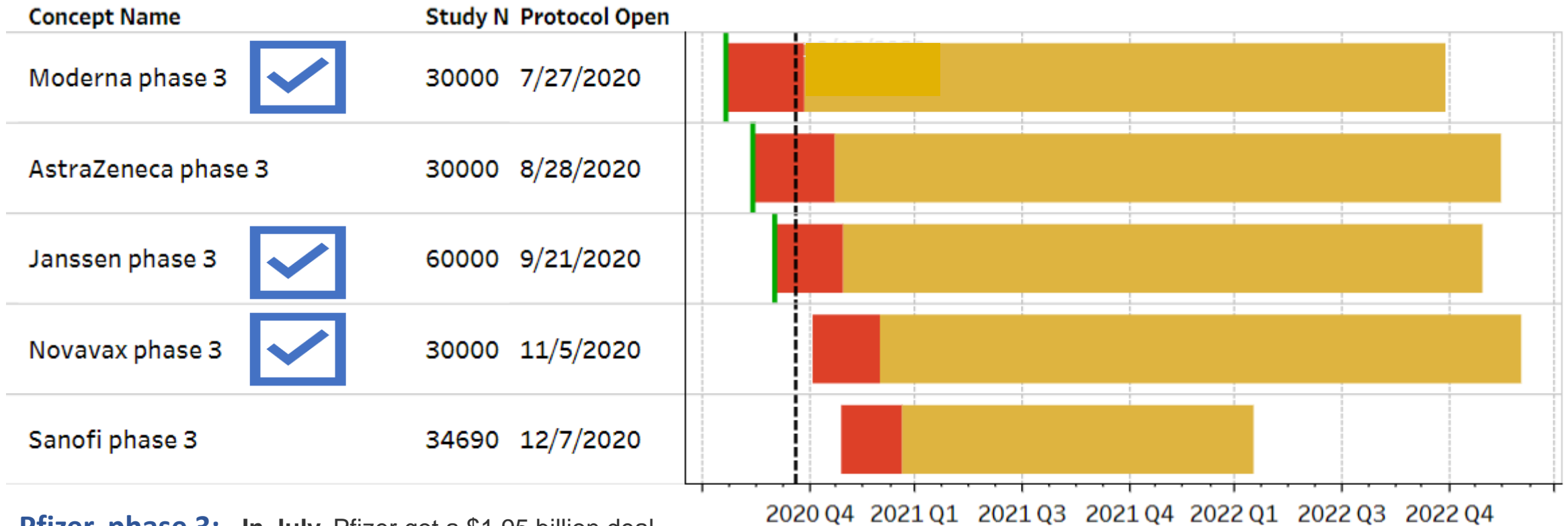
## Legend

- First participant enrolled
- Later phase: Enrollment period
- Later phase: Followup period

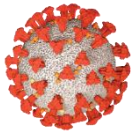


# Phase 3 Vaccine Pipeline




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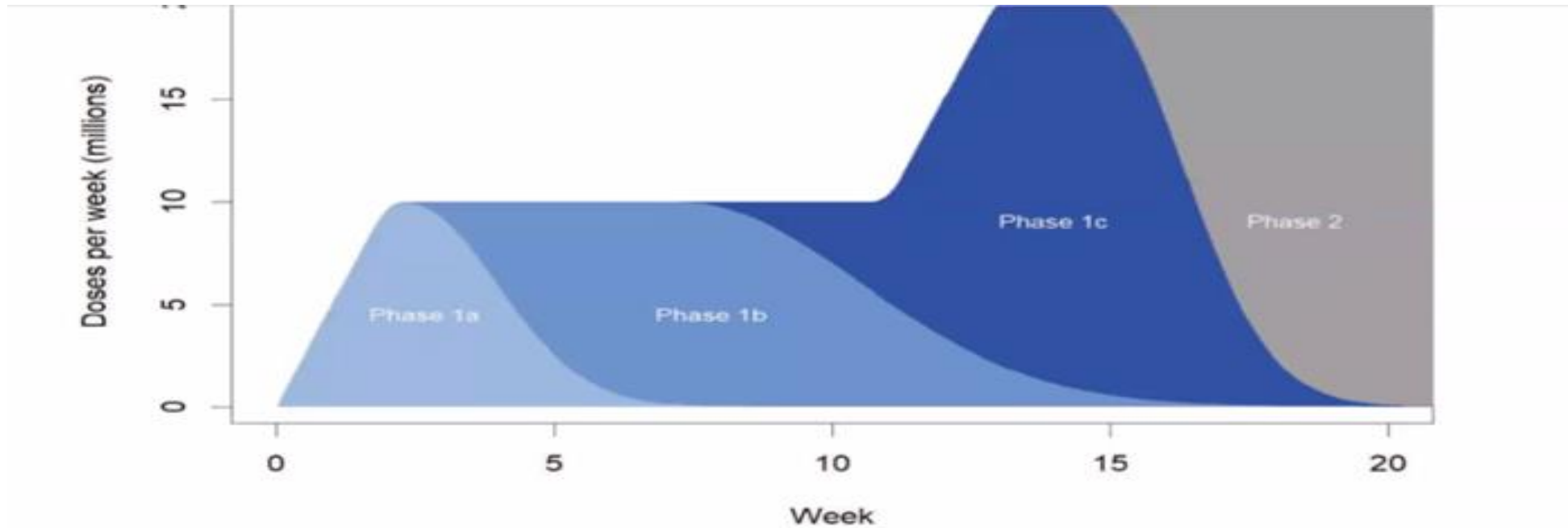
**Pfizer, phase 3:** In July, Pfizer got a \$1.95 billion deal with the government's Operation Warp Speed, the multiagency effort to rush a vaccine to market, to deliver 100 million doses of the vaccine.



## Legend

-  First participant enrolled
-  Later phase: Enrollment period
-  Later phase: Followup period

# Prioritizing the Distribution of Available Doses of Vaccine- Sample Schema Timeline



**Phase 1a:** XX Million Doses

**Phase 1b:** XX Million Doses

**Phase 1c:** XX Million Doses

**Phase 2:** XX Million Doses

## **Priority Groups:**

Healthcare Workers, Long Term Care Facility Patients  
Essential Workers; Disproportionately affected populations  
Elderly, high risk conditions

- 
- 

**General population-anyone wanting vaccine**

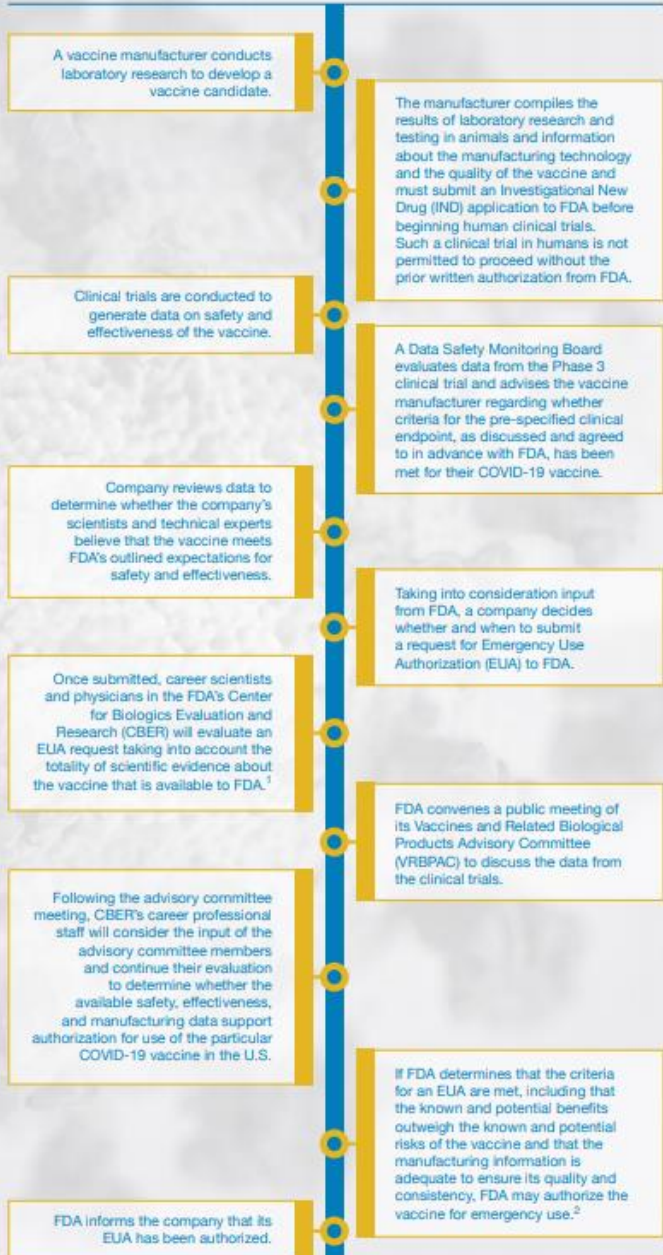
# Vaccine Approval Process

What does this mean— Emergency Use Authorization?

<sup>1</sup> Part of FDA's evaluation of an EUA request for a COVID-19 vaccine includes evaluation of the chemistry, manufacturing, and controls information for the vaccine. Sufficient data should be submitted to ensure the quality and consistency of the vaccine product. FDA will use all available tools and information, including records reviews, site visits, and previous compliance history, to assess compliance with current good manufacturing practices.

<sup>2</sup> FDA has made clear in its October 2020 guidance entitled Emergency Use Authorization for Vaccines to Prevent COVID-19, that, for a COVID-19 vaccine for which there is adequate manufacturing information to ensure its quality and consistency, issuance of an EUA would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.

## The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization



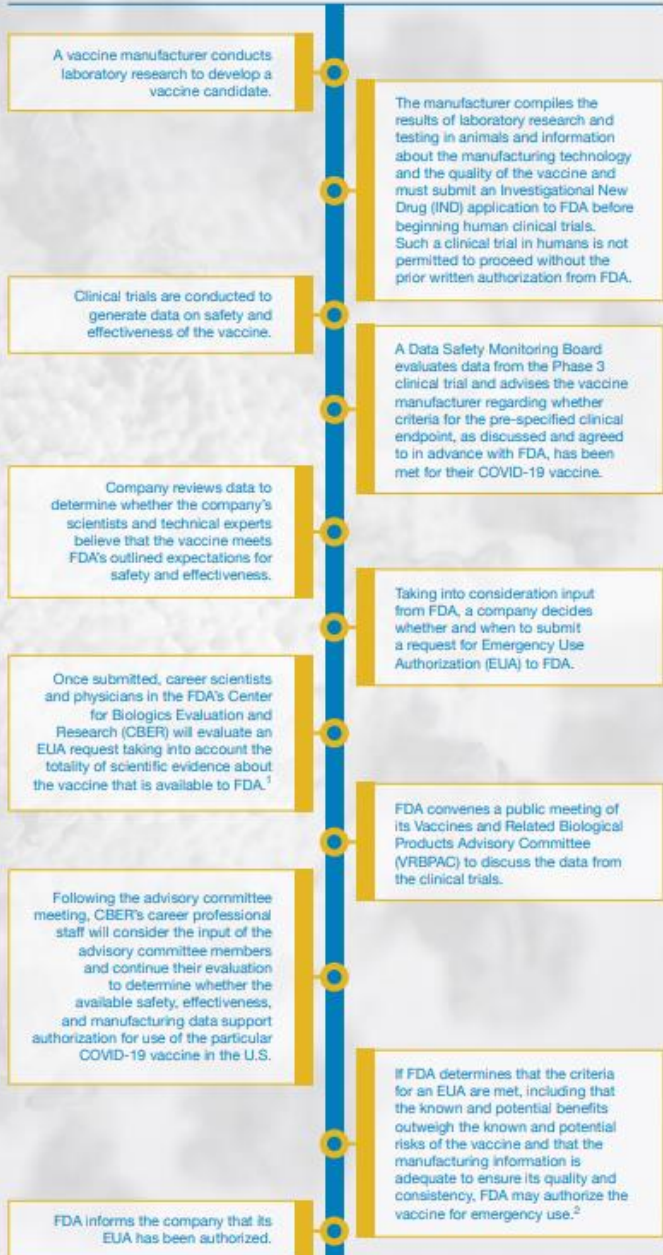
1. **A vaccine manufacturer** conducts LABORATORY research to develop vaccine candidate
2. **Submission of Investigational New Drug (IND) to FDA** (lab testing/animal models)
3. **Clinical Trials-** safety/effectiveness
4. **Data Safety Monitoring Board** evaluates data from the Phase 3 clinical trial-->clinical endpoint for COVID-19 vaccine.
5. **Company reviews data** →FDA's expectations met for safety and effectiveness.
6. **Emergency Use Authorization (EUA) to FDA-** Company decides whether and when to submit a request
7. **FDA's Center for Biologics Evaluation and Research (CBER)** will evaluate an EUA request
8. **FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC)** discuss the data from the clinical trials
9. **CBER looks at available safety, effectiveness, and manufacturing data** support authorization for use of the particular COVID-19 vaccine in the U.S
10. **Emergency Use Authorization decision:**FDA evaluates data on potential benefits/risks
11. **FDA informs of Emergency Use Authorization (EUA)**



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1. **A vaccine manufacturer** conducts LABORATORY research to develop vaccine candidate
2. **Submission of Investigational New Drug (IND) to FDA** (lab testing/animal models)
3. **Clinical Trials-** safety/effectiveness **NOVAVAX- (DECEMBER 1\_, 2020)**
4. **Data Safety Monitoring Board** evaluates data from the Phase 3 clinical trial-->clinical endpoint for COVID-19 vaccine.
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10. **Emergency Use Authorization decision:** FDA evaluates data on potential benefits/risks
11. **FDA informs of Emergency Use Auth** **PFIZER- (DECEMBER 11, 2020)** **(EUA)**



# Updates (as of December 14, 2020)

- **December 10, 2020:** PFIZER-BIONTECH COVID-19 VACCINE (BNT162, PF-07302048) - Vaccines & Related Biological Products Advisory Committee meeting
- **On December 11, 2020,** the U.S. Food and Drug Administration issued the first emergency use authorization (EUA) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals **> 16 years** of age. The emergency use authorization allows the **Pfizer-BioNTech COVID-19 Vaccine** to be distributed in the U.S.
- If FDA approves, **ACIP** will quickly hold a public meeting to review all available data about that vaccine
  - **December 11 and 13-** Scheduled
- **December 14, 2020:** A critical care nurse, Sandra Lindsay on Monday became **the first American to get a coronavirus shot** since the Pfizer-BioNTech vaccine was [authorized](#) by the government three days earlier.  
[“It didn’t feel any different than taking any other vaccine,”](#) Lindsay said afterward, sitting in a blue armchair at Long Island Jewish Medical Center in hard-hit New York
- **December 17, 2020:** The U.S. Food and Drug Administration has scheduled a [meeting of its Vaccines and Related Biological Products Advisory Committee \(VRBPAC\) on Dec. 17](#) to discuss the request for emergency use authorization (EUA) for a COVID-19 vaccine from **Moderna Inc.** (for **≥18 years** of age)
  - VRBPAC members provide advice to the agency, which may include advice on the safety and effectiveness data submitted in the EUA request, final decisions on whether to authorize the vaccine for emergency use are made by the FDA

# A most remarkable, landmark event(s)...

- **A UK grandmother**, Margaret Keenan, who turns 91 next week, said the injection she received at 06:31 GMT (December 8) was the "best early birthday present".
- **A US critical nurse**, Sandra Lindsay, is first US person to receive CoVID-19 Vaccine. ~9:00 AM EST (December 14)



# Distribution Timeline

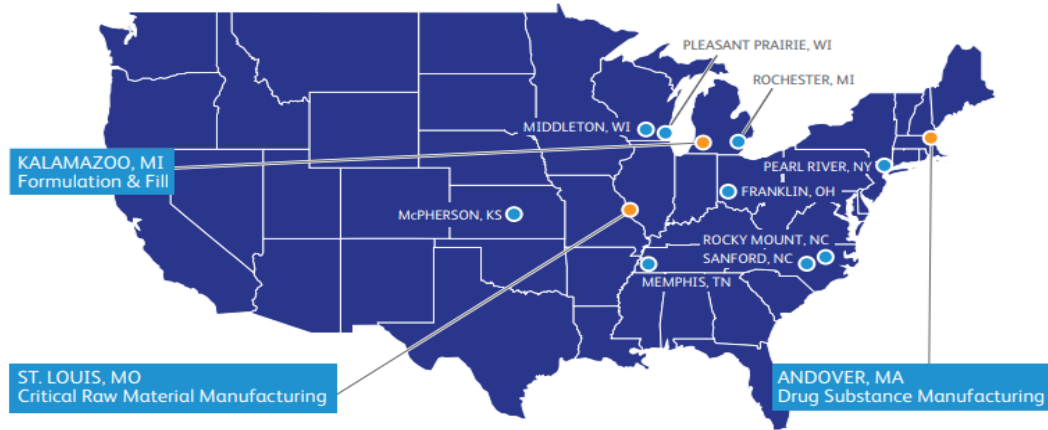
***Factors that Impact Distribution- Post- EUA Approval***

# Factors in the Distribution/Acceptance of CoVID-19 Vaccine

- **47% of 1,117 adults said they plan to get vaccinated**, while 26% said they did not plan to get a vaccine and 27% were still unsure (Associated Press).
- **Handling requirements** for vaccine
  - the Pfizer vaccine (mRNA is not stable, requires -94 degrees Fahrenheit)
  - PCPs will likely not receive it for distribution
- **State Health Departments** → Identify CoVID-19 Vaccine Distribution Locations
  - Health care providers
  - Pharmacies,
  - Physician offices and other types of clinics
- Health authorities in the United Kingdom have advised against giving Pfizer and BioNTech's COVID-19 vaccine to individuals with a history of allergic reaction
- **Ascertaining Demand v. Availability:** (24 M x 2 doses= 48 M doses needed)
  - 21 million U.S. health care personnel work
  - 3 million adults reside in LTCFs, which include skilled nursing facilities, nursing homes, and assisted living facilities

# Pfizer's story...

Pfizer has manufacturing and distribution sites across the U.S. Initially for the COVID-19 vaccine program, we are leveraging three of them:



## How It Happens

Pfizer's manufacturing and supply chain professionals have been taking several steps to accelerate the scale-up and manufacture four of the most promising vaccine leads:

- Exchanging technology to enable rapid facility, equipment and process design planning
- Ordering materials and starting to manufacture potential vaccine candidates
- Putting two parallel supply chains in place for appropriate redundancies
- Modifying facilities for the vaccine candidates and re-prioritizing capacity
- Hiring and training staff to give our operations even more support and flexibility
- Investing at risk so we can quickly produce as many doses of a potential vaccine as possible

## Manufacturing Capabilities

We operate one of the most sophisticated supply chain systems in the industry, with more than 40 Pfizer-owned sites and more than 200 suppliers globally.

We have more than:

28,000  
COLLEAGUES



SUPPLYING  
MEDICINES TO  
125  
COUNTRIES

Producing more than  
**23 billion doses** of  
medications per year,  
including **1.5 billion**  
sterile units



For biologics and vaccines, we have:



7,000  
COLLEAGUES  
IN  
12  
MANUFACTURING  
FACILITIES  
IN  
10  
COUNTRIES

CAPACITY TO  
MANUFACTURE  
MORE THAN  
**500 MILLION**  
**DOSES**  
OF MEDICINES  
AND VACCINES



# ACIP Principles to guide CoVID-19 Vaccine Rollout Plan (with limited supply)

- **Maximize benefits and minimize harms** — Respect and care for people using the best available data to promote public health and minimize death and severe illness.
- **Mitigate health inequities** — Reduce health disparities in the burden of COVID-19 disease and death, and make sure everyone has the opportunity to be as healthy as possible.
- **Promote justice** — Treat affected groups, populations, and communities fairly. Remove unfair, unjust, and avoidable barriers to COVID-19 vaccination.
- **Promote transparency** — Make a decision that is clear, understandable, and open for review. Allow and seek public participation in the creation and review of the decision processes.
- Learn more about [ACIP's Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine](#).
- Groups considered for early vaccination if supply is limited
- Before making an official recommendation, ACIP considered four groups to possibly recommend for early COVID-19 vaccination if supply is limited:
  - [Healthcare personnel](#)
  - [Workers in essential and critical industries](#)
  - [People at high risk for severe COVID-19 illness due to underlying medical conditions](#)
  - [People 65 years and older](#)

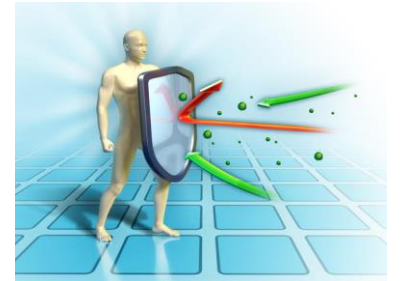
# How to Determine Vaccine Efficacy...And, What Does It Mean?



# What are we hoping to learn from these studies?

In general, the vaccines we are studying seek to answer the following main questions:

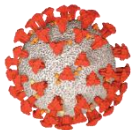
- Does the vaccine create an immune response that protects people against moderate to severe COVID-19 illness? Or can the immune response protect against infection with SARS-CoV-2? **VACCINE EFFICACY**



- Does the vaccine continue to show that it is safe when tested in thousands of people?



- Do the vaccine side effects continue to be well tolerated?



# Most common side effects with Moderna and Pfizer's vaccines

## Moderna

**(mRNA 1273)** 30,000 participants

- Vaccine Efficacy: **94.5%**
- Most common solicited adverse reactions included injection site pain, fatigue, myalgia, arthralgia, headache, and erythema/redness at the injection site.
- Solicited adverse reactions increased in frequency and severity in the mRNA-1273 group after the second dose.

**(NT162b2)** 43,661  
participants

- Vaccine efficacy rate of **95%**, with no serious safety concerns observed to date
- Most frequently observed adverse events were injection site pain, fatigue (3.8%), headache (2%) and muscle pain.

# VACCINE EFFICACY

Group	Group Size	Number Infected	Infection Risk	If in U.S. Population
Placebo	21,830	162	$\frac{162}{21830} = 0.74\%$	2,427,200 ( about 2.5 million)
Vaccine	21,830	8	$\frac{8}{21830} = 0.04\%$	131,200 (131 thousand)

Group	Group Size	Number Infected	Infection Risk	If in U.S. Population
Placebo	21,830	162		
Vaccine	21,830	8		

Vaccine reduced the infection risk by 0.7 percentage points (less than 1 percentage point)

Difference of Infection Risks between Placebo and Vaccine (0.7%) by the infection risk of the placebo group (0.74%)

$$\frac{0.7\%}{0.74\%} \approx 95\%$$

- [What Does 95% Effective Mean? Teaching the Math of Vaccine Efficacy - The New York Times \(nytimes.com\)](https://www.nytimes.com/2020/12/01/health/vaccine-efficacy.html)

This tells you that, under the same conditions as the study,

the vaccine reduces the risk of infection by 95 percent. \*Moderna's study results similar. If 100 cases of symptomatic infection, 90 of them in the placebo group.

PFIZER'S DATA FROM PHASE 3 TRIAL

# Help find a vaccine for COVID-19!

## We're looking for:

- Adults aged 18 and older
- People who are more likely to be exposed to COVID-19, including:
  - People with underlying medical conditions
  - People with greater chances of exposure at their job
  - People who live or work in elder-care facilities
  - People over age 65
  - People who work in jails or prisons
  - People from racial and ethnic groups that have been impacted in greater numbers by the epidemic, such as African Americans, Latinx, and Native Americans

If you decide to join a COVID-19 prevention study, you will be compensated for your time.

You **CANNOT** get infected with SARS-CoV-2 or get COVID-19 illness from the study vaccine.

www.[CoronavirusPreventionNetwork.org](http://CoronavirusPreventionNetwork.org)



COVID-19  
Prevention Network



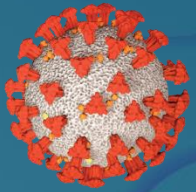
## Questions?

## Call 1-888-788-0644

Goto: [www.CoronavirusPreventionNetwork.org](http://www.CoronavirusPreventionNetwork.org);  
Register with 'MORE' and MSM's CoVID-19  
Vaccine Unit team member will contact you



Vaccines don't save lives,  
vaccinations do.



COVID-19  
Prevention Network

Questions?

A medical syringe with a green plunger and needle is positioned diagonally across the frame. In the foreground, a small glass vial with a silver cap and a label that reads "VACCINE COVID-19" is visible. The background is a solid teal color. A white horizontal bar is overlaid in the center, containing the text "THE WAY FORWARD".

# THE WAY FORWARD





**DR. DAVID HOLLAND**

**Chief Clinical Officer, Fulton County Board of Health**

# *The COVID-19 Vaccine: The Facts and the Way Forward*

## *The equity implications of Georgia's Plan*

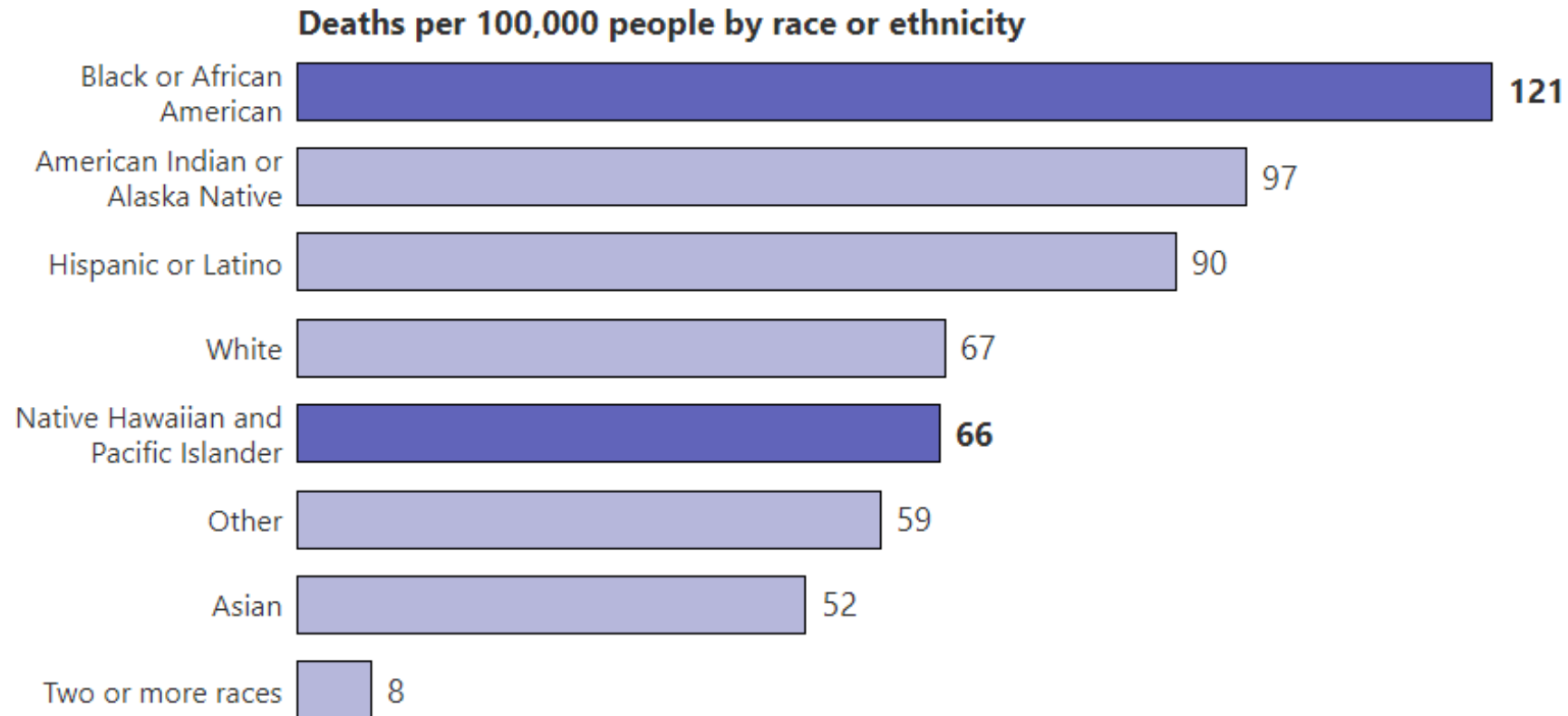
Megan Douglas, JD

Assistant Professor, Community Health and Preventive Medicine

Health Policy Director, National Center for Primary Care

Morehouse School of Medicine

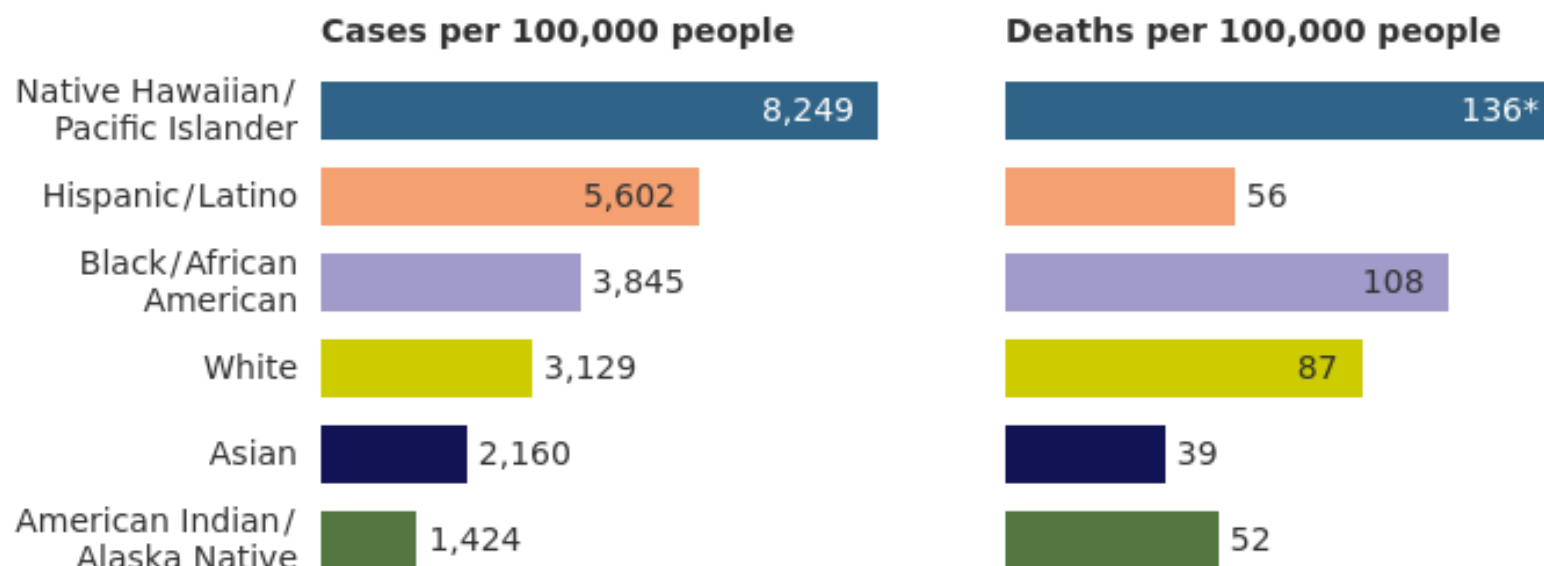
# Nationwide, Black people are dying at 1.8 times the rate of white people.



The COVID Racial Data Tracker. <https://covidtracking.com/race>



In **Georgia**, through December 13, Native Hawaiians/Pacific Islanders were most likely to have contracted COVID-19 and were also most likely to have died.



**Notes:** Georgia has reported race and ethnicity data for 82% of cases and 91% of deaths. Graphic only includes demographic groups reported by the state. Race categories are mutually exclusive and defined as not Hispanic or Latino.

\* Based on fewer than 10 deaths among members of this race/ethnicity. Interpret with caution.

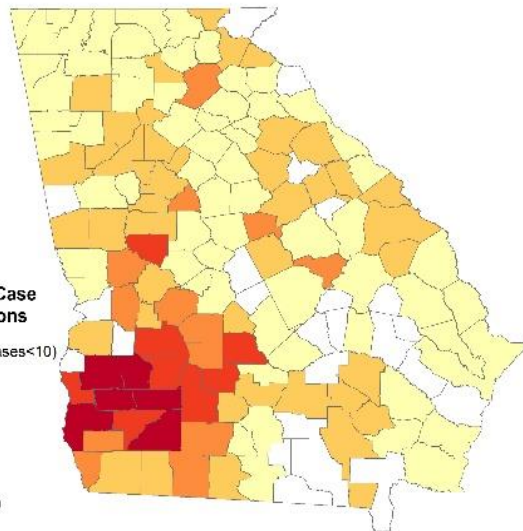
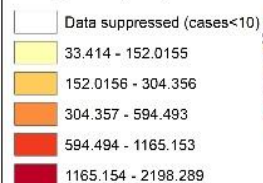


COVID case & death rates:  
Johns Hopkins Coronavirus  
Resource Center  
(December 9, 2020)

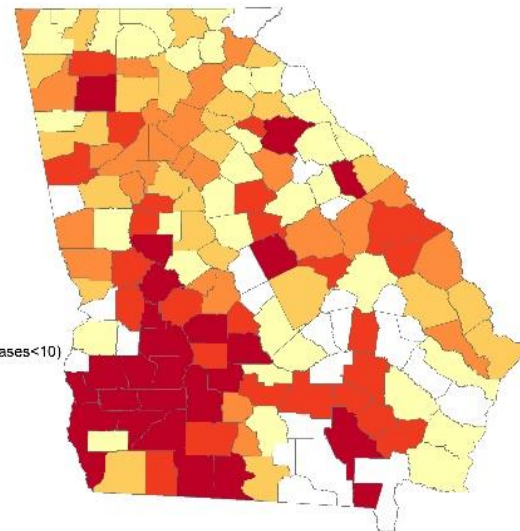
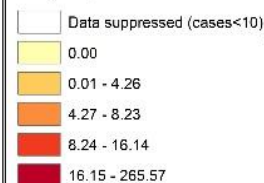
Primary Care Health  
Professional Shortage Area  
(PC HPSA): Health  
Resources and Services  
Administration, Area Health  
Resource File

% Black population: US  
Census Bureau, American  
Community Survey

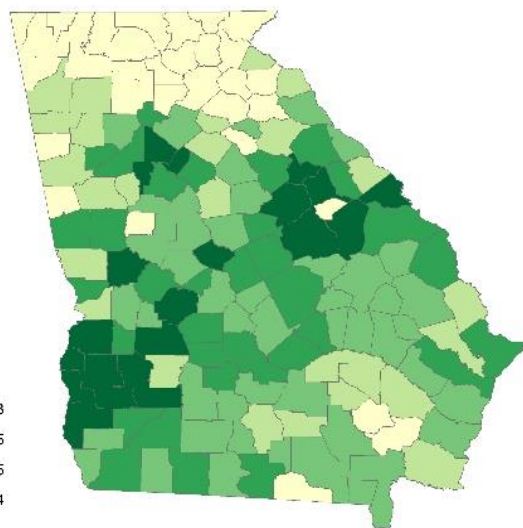
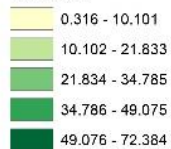
COVID-19 Confirmed Case  
Rate per 100,000 persons



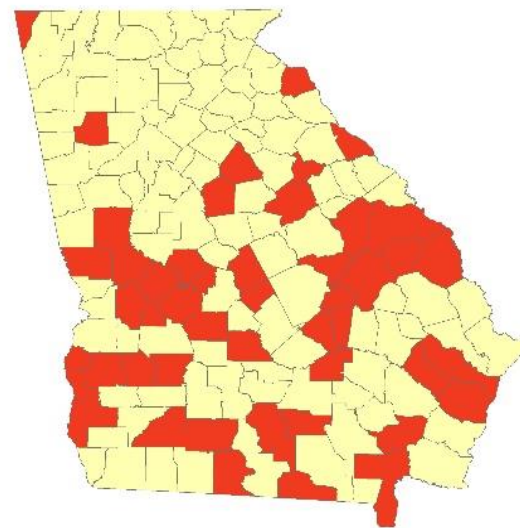
COVID-19 deaths per  
100,000 persons



Black, %



Primary care HPSA



NCPC  
National Center  
for Primary Care



# 'An unbelievable chain of oppression'. America's history of racism was a preexisting condition for COVID-19

In a six-part series, USA TODAY investigates how racist policies of the past and present have fueled high COVID-19 deaths in communities of color.

Alan Gomez, Wyattte Grantham-Philips, Trevor Hughes, Rick Jervis, Rebecca Plevin, Kameel Stanley, Dennis Wagner, Marco della Cava, Deborah Barfield Berry, and Mark Nichols, USA TODAY

Updated 9:12 p.m. EDT Oct. 21, 2020

County	State	People of color	Death rate
1 Hancock	GA	75.8%	45.7
2 Galax	VA	24.7%	42.2
3 Randolph	GA	65.1%	38.1
4 Terrell	GA	64.5%	35
5 Neshoba	MS	41.4%	34
6 McKinley	NM	91.2%	33.4
7 Emporia	VA	77.5%	31.6
8 Early	GA	54.4%	30.9
9 Holmes	MS	84.4%	29.9
10 Jenkins	GA	44%	28.3
11 New York City*	NY	67.9%	28.1
12 Essex	NJ	69.2%	26.7

## CORONAVIRUS

### Race And COVID-19: Stark Disparities In Rural Georgia

ANDY MILLER, GEORGIA HEALTH NEWS • OCT 18, 2020



\*\* America's education and economic systems are still unequal, disproportionately leaving people of color out of higher-wage jobs. When COVID-19 struck, more people of color were serving as [essential workers](#) directly in the path of the virus.

\*\* Decades of discrimination in housing has put people of color into dense neighborhoods, fueling the virus' spread. Those neighborhoods tend to lie in "[food deserts](#)," leading to diabetes, obesity and heart disease that make people more likely to die from the coronavirus.

\*\* [Environmental policies](#) pursued at the expense of the poor has poisoned the air they breathe, fueling cancers and leaving communities weakened in the path of the virus. A lack of federal funding left the most vulnerable communities [cut off from health care](#) at the most critical moment.



NCPC  
National Center  
for Primary Care

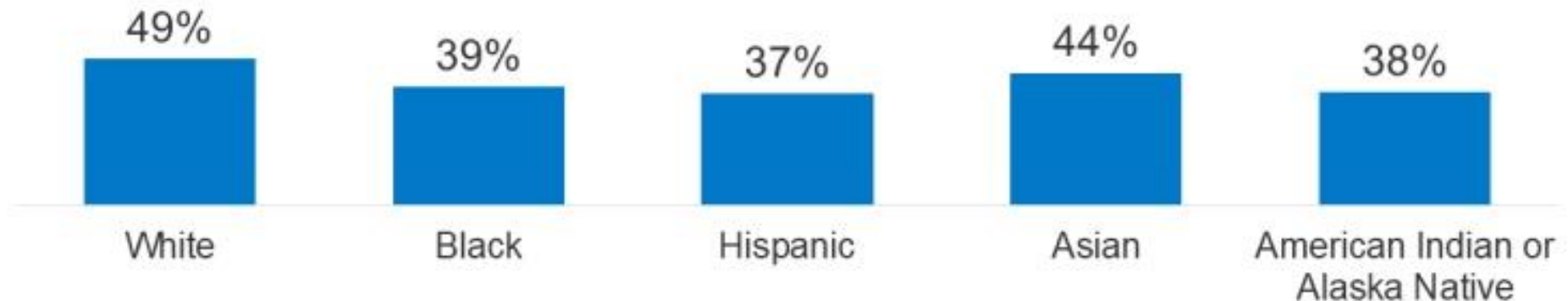
[www.msm.edu/ncpc](http://www.msm.edu/ncpc)

 **MOREHOUSE**  
SCHOOL OF MEDICINE

Figure 1

## Influenza Vaccination Rates among Adults by Race and Ethnicity, 2018-2019 Season

Influenza Vaccination Rates among Adults by Race and Ethnicity, 2018-2019 Season



NOTE: Adults are age 18 and older. Persons of Hispanic origin may be of any race but are categorized as Hispanic; other groups are non-Hispanic.

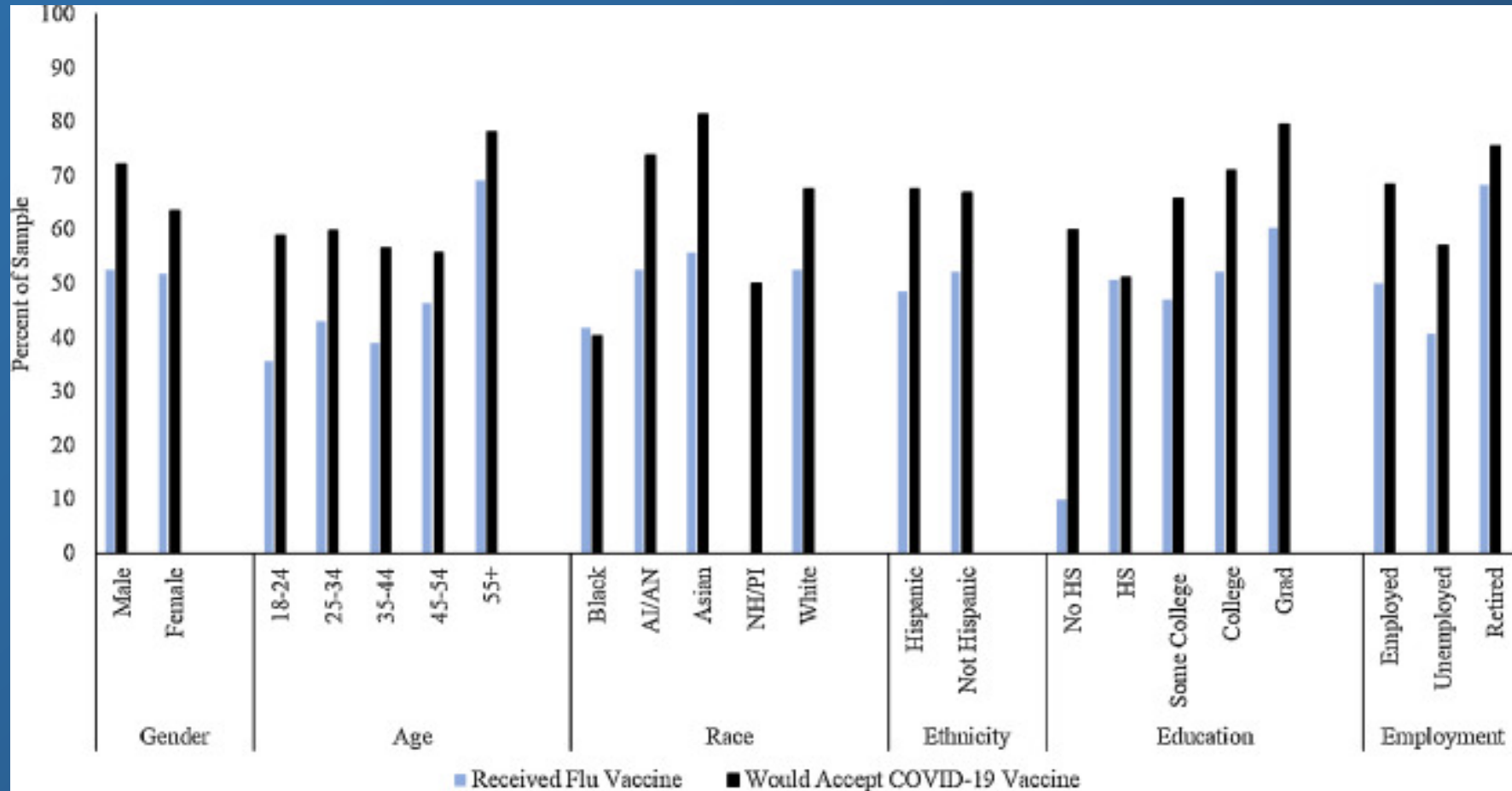
SOURCE: Centers for Disease Control and Prevention, Flu Vaccination Coverage, United States 2018-2019 Season, <https://www.cdc.gov/flu/fluva/view/coverage-1819estimates.htm>

**KFF**





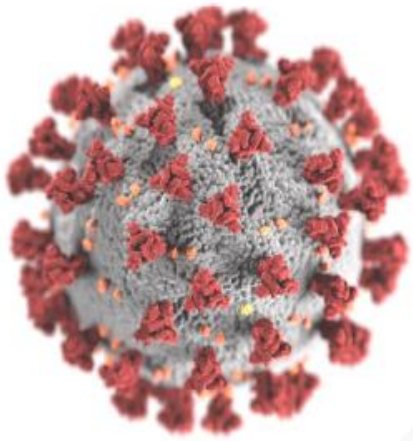
# Comparison by demographic categories of the percent of the sample who reported receiving the influenza vaccine to those would reported they would accept the COVID-19 vaccine



**Abbreviations:** AI/AN: American Indian/Alaska Native, NH/PI: Native Hawaiian/Pacific Islander, Grad: Graduate or Professional Degree, \*Age is listed in years.

Malik AA, McFadden SM, Elharake J, Omer SB. Determinants of COVID-19 vaccine acceptance in the US. *EClinicalMedicine*. 2020 Sep;26:100495.





# COVID-19 Vaccination Plan

GEORGIA

## COVID-19 Vaccine in GA



### Georgia Vaccine Plan

Follow the plan for distribution and administration of the COVID-19 vaccine in Georgia.

 [COVID-19 Vaccine Plan](#) (1.24 MB)



### FAQ on Vaccines

The CDC answers commonly asked questions. Regular updates will be made as needed.

[Frequently Asked Questions](#)



### Are Vaccines Safe?

The U.S. vaccine safety system ensures that all vaccines are as safe as possible. Learn more about

[Vaccine Safety](#)

1. Phased Approach
2. Critical Populations
3. Provider Enrollment
4. Data & Monitoring Plan

<https://dph.georgia.gov/covid-vaccine>

## Phase 1-A

- Healthcare personnel
- First responders
- High-risk/underlying conditions
- Essential workers

## Phase 1-B

- Police & fire personnel
- Critical workforce employees
- Adults 65+ with comorbidities

## Phase 1-C

- Adults 65+
- Adults 18-64 with comorbidities

## Phase 2

- Remaining phase 1
- Critical populations
- Others whom vaccination recommended

## Phase 3

- General Population



# Critical Populations (p. 23)

**Risk of acquiring infection:** Higher priority given to individuals who have a greater probability of being in settings where COVID-19 is circulating and exposure to the virus.

**Risk of severe morbidity and mortality:** Higher priority given to individuals with a greater probability of severe disease or death if they acquire infection.

**Risk of negative societal impact:** Higher priority is given to individuals with societal function, and upon whom other people's lives and livelihood depend directly and would be imperiled if they fell ill. It does not consider their wealth or income, or how readily an individual could be replaced in a work setting, given labor market conditions.

**Risk of transmitting the disease to others:** Higher priority is given to individuals who have a higher probability of transmitting the disease to others.





Thank you for subscribing. Choose from a variety of newsletters to stay informed.

With release of  
COVID-19 vaccine  
imminent,  
distribution plan to  
be tested



Facilities with more money and resources to plan likely will fare better than those without, at least initially.

Possibly left out, at least in the initial distributions, will be many small hospitals and other types of providers that lack the workers and resources needed to carry out the complex logistics of mass vaccination. That may be one reason why 2,000 health care providers expressed interest in the state vaccination program, but only 300 have completed the enrollment packet so far.

An added complication is that not everyone will want to be among the first vaccinated. According to a late October poll by the American Nurses Association, only one-third of the 13,000 nurses surveyed said they would voluntarily take a vaccine, another third said they wouldn't and the rest said they were unsure.

Georgia's cut of the federal money distributed so far is \$6.2 million, or about 58 cents per resident, according to the Kaiser Family Foundation. These funds are needed to help pay for staffing to administer the vaccine, data information system upgrades, cold supply chain management, vaccination campaigns and arranging for additional vaccination sites.



# Georgia Testing Data – November 2, 2020

Rank by population	COUNTY	% of Tests with Missing R/E Data	Population	Tests with R/E data	All tests
1	FULTON	63.3	1,021,902	180,975	493,482
2	GWINNETT	71.3	902,298	78,077	271,918
3	COBB	73.2	745,057	54,264	202,229
4	DEKALB	67.5	743,187	101,198	311,424
5	CHATHAM	77.0	287,049	25,457	110,880
6	CLAYTON	63.1	278,666	31,484	85,355
7	CHEROKEE	73.0	241,910	22,410	82,960
8	HENRY	53.7	221,307	24,354	52,646
9	FORSYTH	67.1	219,880	18,617	56,546
10	RICHMOND	37.8	201,463	47,534	76,400
11	MUSCOGEE	75.4	196,670	14,524	59,159
12	HALL	87.8	195,961	12,756	104,323
13	PAULDING	71.0	155,840	9,358	32,269
14	BIBB	46.8	153,490	27,584	51,849
15	HOUSTON	68.8	151,682	9,714	31,175
16	COLUMBIA	37.2	147,295	22,359	35,590
17	DOUGLAS	74.0	141,840	10,356	39,862
18	COWETA	45.7	140,516	15,802	29,076
19	CLARKE	70.9	124,602	21,255	73,067
20	CARROLL	65.0	116,022	12,441	35,515

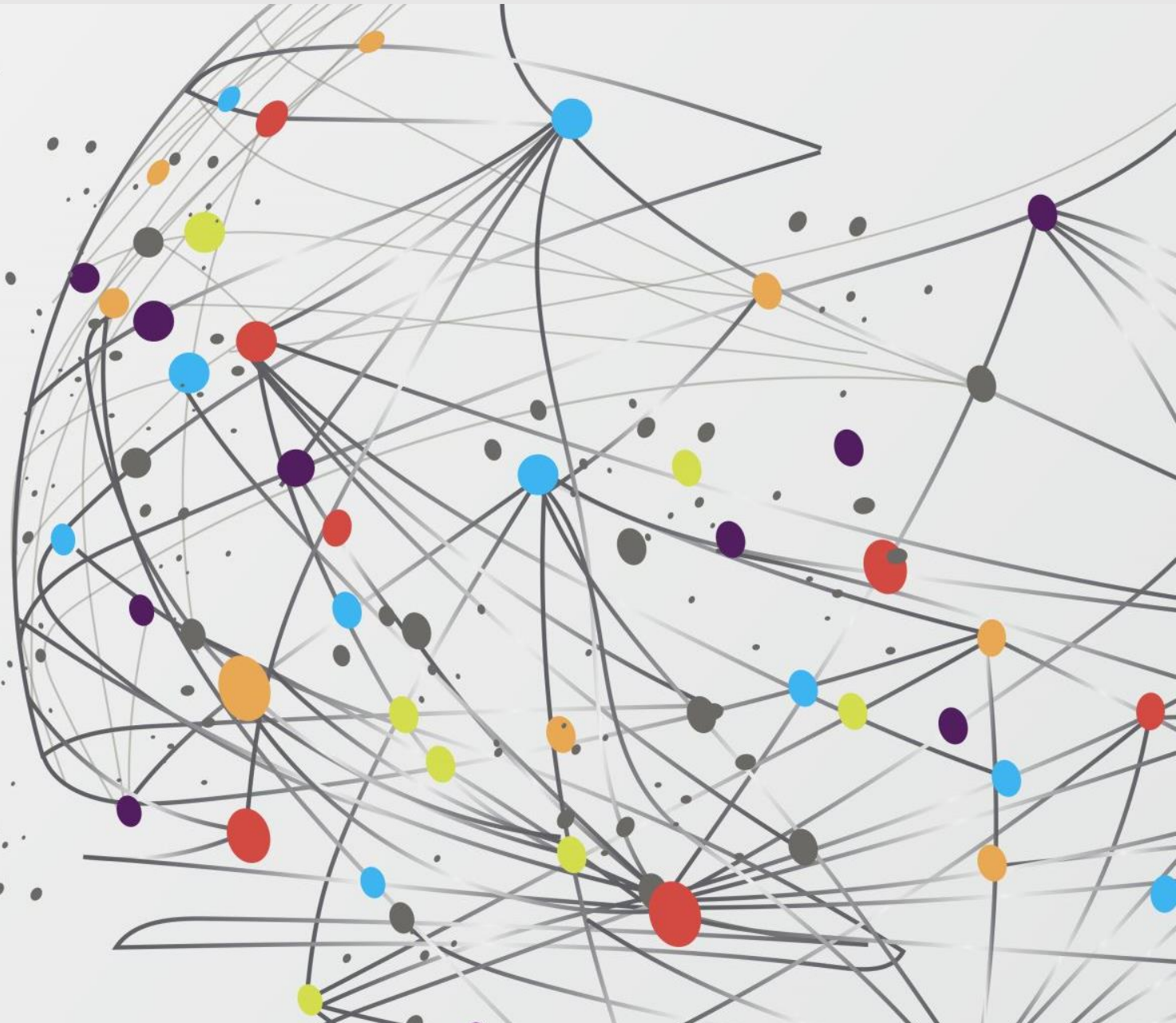


# **DR. TABIA HENRY-AKINTOBI**

**Director, Prevention Research Center, Morehouse School  
of Medicine**



GEORGIA CEAL



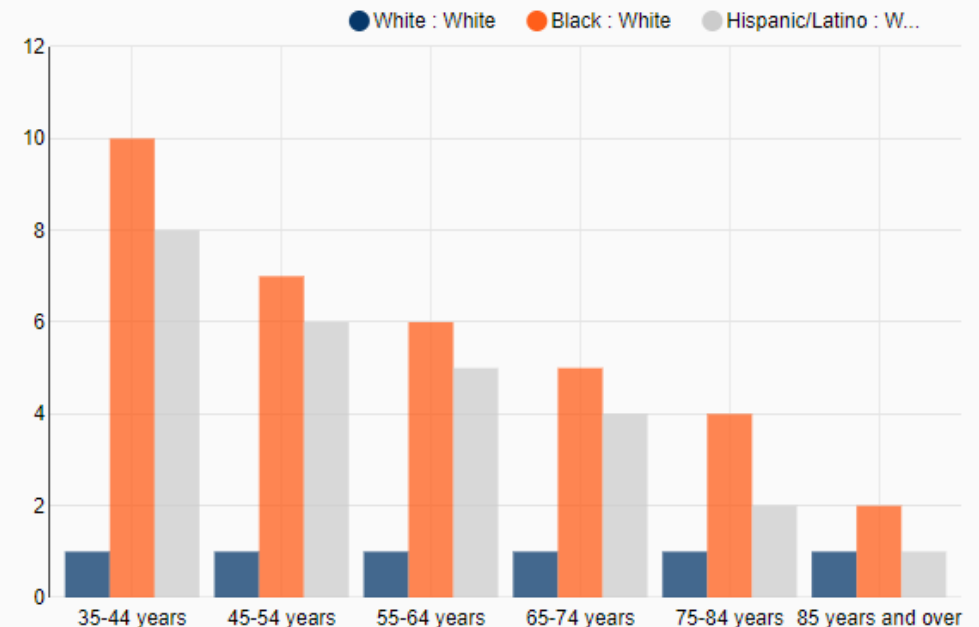
# COVID-19 disease burden and outcome disparity are concentrated in sub-populations

## COVID-19 Disease Burdens

- **Patients aged 60 and above** account for ~60% of hospital and ICU admissions and **~90% of deaths** while representing 20% of population
- **Patients with preexisting conditions** are 6-7 times more likely to be hospitalized and **more than 10 times more likely to die** than patients without preexisting conditions
- **Communities of color** are over-represented in cases and deaths by **~1.5-2x for Latinx and African American populations**, with huge disparities in outcomes for middle age

Figure 2. Huge race gaps in COVID-19 death rates, especially in middle age

Ratio of death rates



Source: CDC data from 2/1/20-6/6/20 and 2018

Census Population Estimates for USA

BROOKINGS

# Reducing the spread



Call your doctor and ask for instructions about how to stay home and be in quarantine.



Practice excellent hygiene habits



Clean frequently touched surfaces and objects



**Cloth face masks**



**Scarves**

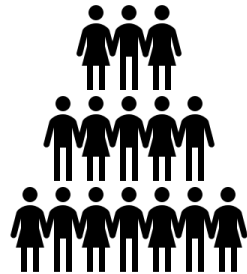
Wear cloth face coverings that cover your mouth and nose



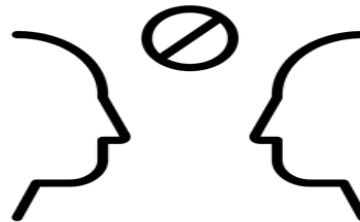
**Bandanas**



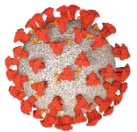
Stay home



Large gatherings are prohibited

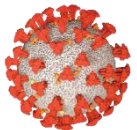


Stay 6 feet apart from other people, and avoid contact with people who are sick



# Summary and the Way Forward

- **Communities most impacted by COVID-19 have long-standing experiences of social and structural inequities that negatively impact health and wellbeing**
- **Community Engagement efforts are critical to ensure:**
  - Well-informed communities
  - Community support for research
  - Meaningful relationships
  - Reciprocal partnerships
  - Increased trust
- **To promote equitable representation in COVID-19 trials, we must**
  - Recognize the importance of enrolling Black, Native and Latinx participants
    - Studies must report demographics of trial enrollment while they are ongoing
  - Provide appropriate funding to trial sites to support diversity initiatives
    - Translations, reimbursement for transportation, diverse research workforce, etc.
  - Address research mistrust by engaging communities early and often throughout the process
  - Paying people back for trusting in medical research = equitable vaccine access once approved





# BLUF: The Bottom-Line Up Front

*CEAL: Community Engagement Alliance Against COVID-19 Disparities*

**is an NIH-wide effort that support statewide efforts to:**

1. Conduct urgent community-engaged research and outreach focused on COVID-19 awareness and education to address misinformation and mistrust; and
2. Promote and facilitate inclusion of diverse racial and ethnic populations in clinical trials (prevention, vaccine, therapeutics), reflective of the populations disproportionately affected by the pandemic.



National Institutes of Health

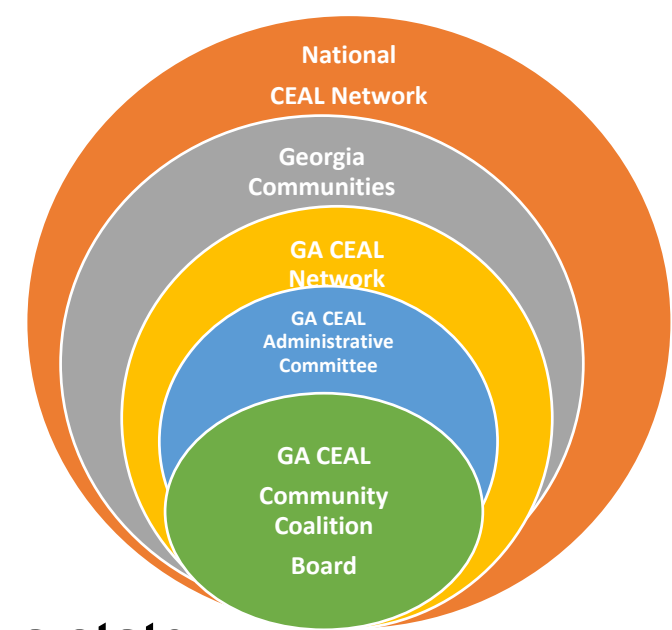


## Georgia CEAL: (Garnering Effective Outreach and Research in Georgia for Impact Alliance) CEAL

- Goal: To **understand** factors that contribute to the disproportionate burden of COVID-19 in underserved communities **and establish effective, community-engaged research and outreach response strategies**

# Georgia CEAL Community Coalition Board

The Georgia CEAL will be governed by a state-representative, community-majority Community Coalition Board (CCB) designed to ensure that research and outreach processes and findings are translated with, co-created by, and relevant to communities towards effective COVID-19 education, outreach, communication, and research, and sustainability.





# Georgia CEAL Community Coalition Board –To Date!

Georgia CEAL Community Coalition Board	
Organization	Academic(A) /Community (C)
Agape	C
American Academy of Pediatrics	C
Andrew J Young Foundation	C
Atlanta Regional Collaborative for Health Improvement	C
Atlanta Housing Authority	C
Atlanta NAACP	C
Community Physicians' Network	C
Division of Aging Services	C
Fellowship Missionary Baptist Convention of GA	C
Georgia Campaign for Adolescent Power & Potential	C
Gateway Center	C
Georgia Cancer Control Consortium	C
Georgia Core	C
Georgia Watch-CHW Coalition	C
Georgia Primary Care Association	C
Henry County Department of Public Health	C
Hispanic Health Coalition of Georgia	C
Latino Community Fund of Georgia	C
Links	
March of Dime-Georgia Market	C
Phoebe Network of Trust	C
Sickle Cell Foundation of Georgia	C
Sedessie Spivey, Dekalb County Board of Health	C
Katherine Lovell, Southside Medical Center	C
Tabia Henry Akintobi, PhD, Morehouse School of Medicine	MSM-A
Lilly Immergluck, MD	MSM-A
Robert Bednarczyk, DrPH, MPH, Emory University	EU-A

# GEORGIA CEAL PRIORITIES

- ▶ Establish the Georgia CEAL as a statewide community engagement hub for COVID-19 mitigation and future public health emergencies
- ▶ Identify areas to disseminate COVID-19 educational materials, messages and vaccine uptake interventions
- ▶ Identify beliefs leading to vaccine hesitancy around COVID-19
- ▶ To develop and disseminate culturally sensitive, scientifically based information COVID 19 vaccine information toward vaccine readiness and participation



## Georgia CEAL Overarching Activities

- Participate in GEORGIA CEAL activities through linkages to community compensated participation in:
  - ▶ Listening/Education Sessions
  - ▶ Interviews
  - ▶ Focus groups
  - ▶ Surveys
  - ▶ Health Communications Testing and Potential Campaign Promotion



# GEORGIA CEAL Anticipate Outcomes

## Anticipated Outcomes

- Improved Attitudes, Perceptions and Knowledge on COVID-19 and Related Research
- **Systematic Engagement of Respected Community Touchpoints and Partners Best Leveraged** to Promote Culturally Sensitive COVID-19 Prevention, Mitigation and Risk Messaging and Their Existing Services
- Improved COVID-19 Messages
- Improved Vaccine Intention, Confidence and Trust and Increased Vaccine Trial Uptake



# Invitation and Collaboration Opportunity

- Invitation of partners/community networks to engage in the community engaged listening, outreach and research
- Co-sponsor forums to elevate and inform towards COVID-19 education, factual information and responsiveness related to community vaccine readiness and participation





# Contact Information



**Morehouse School of Medicine  
Prevention Research Center**

720 Westview Drive, SW, Atlanta, GA 30310

Tabia Henry Akintobi, PhD, MPH

Phone: 404-752-1144

[takintobi@msm.edu](mailto:takintobi@msm.edu)

[www.msm.edu/prc](http://www.msm.edu/prc)



# KATHRYN LAWLER

Executive Director, ARCHI



**Poll Question: What will you do to encourage others to take the vaccine?**



# UPCOMING

---

**NOW:** Let your local public health director know how they can prioritize equity in their vaccine plans : <https://p2a.co/HVIFh77>

If you want to join and share information about the virus and the vaccine sign up!  
[www.archicollaborative.org](http://www.archicollaborative.org)

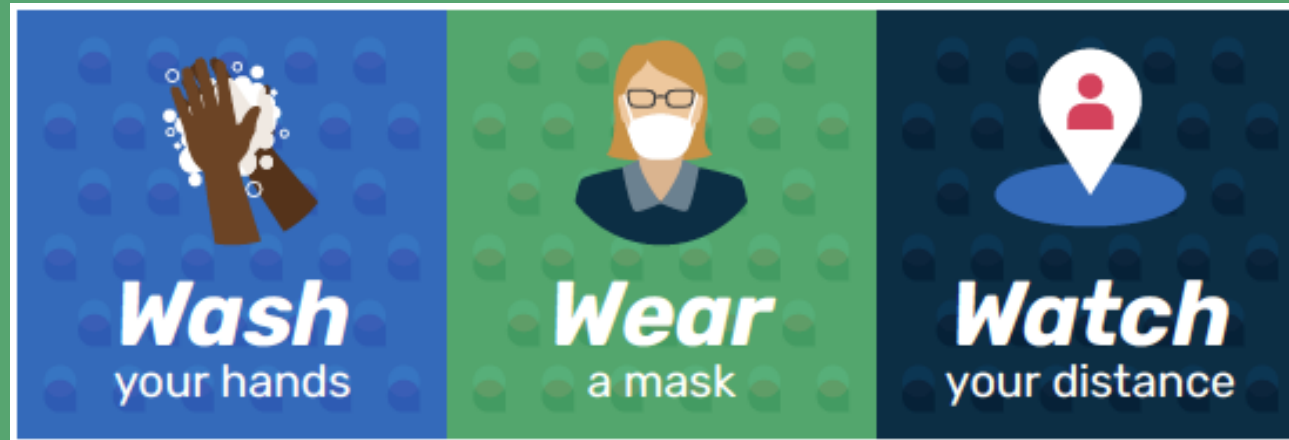


Georgians for a Healthy Future  
[Health Care Unscrambled 2021](#)  
January 7<sup>th</sup>, 8<sup>th</sup>, and 14<sup>th</sup>

Georgia Budget and Policy Institute  
[Insights Policy Conference](#)  
January 22<sup>nd</sup> and 29<sup>th</sup>



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# HAVE A HAPPY AND SAFE HOLIDAY SEASON!!