

COVID-19 Vaccine Studies

Health Commission

September 15, 2020

What could a COVID-19 vaccine do?

Benefit the individual

- ➔ Reduce the severity of illness
- ➔ Prevent infection

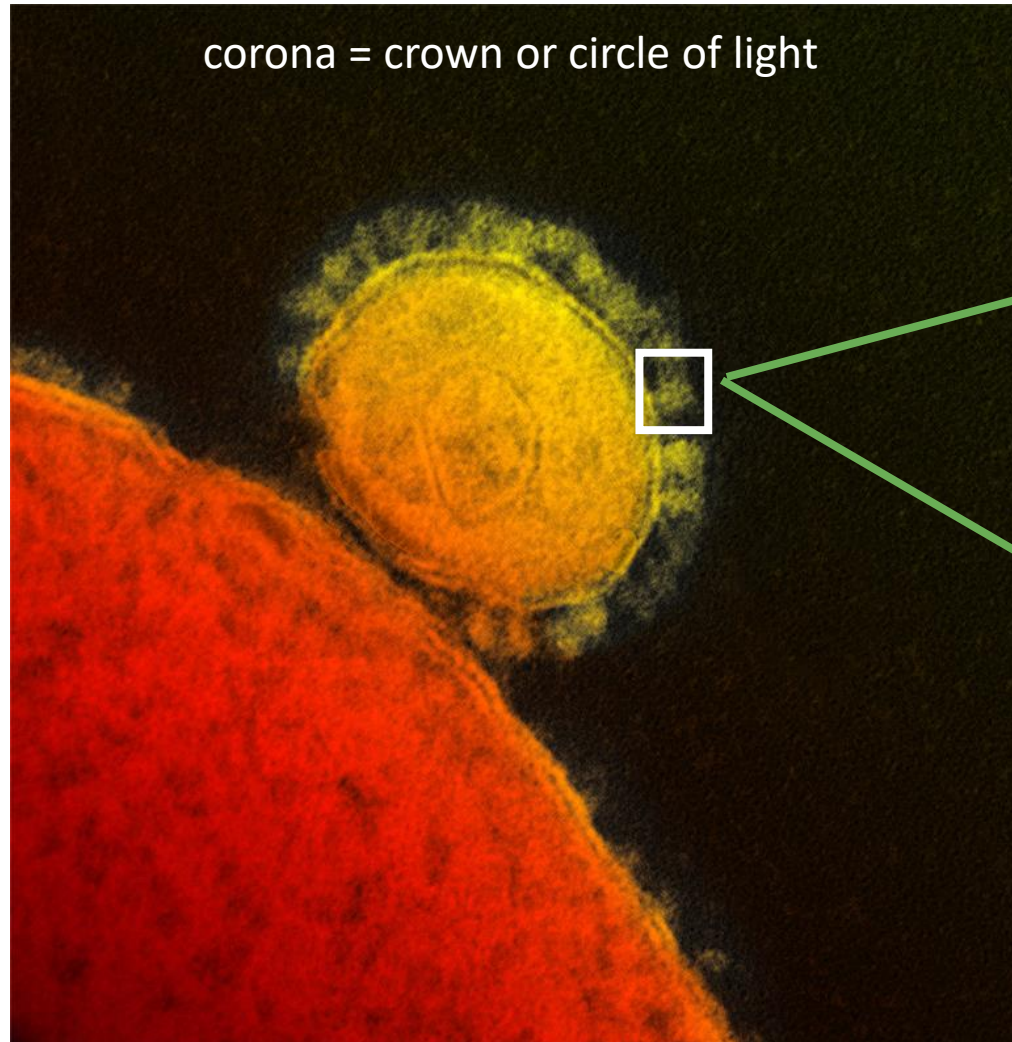
Benefit the community

- ➔ Reduce transmission
- ➔ Healthier communities

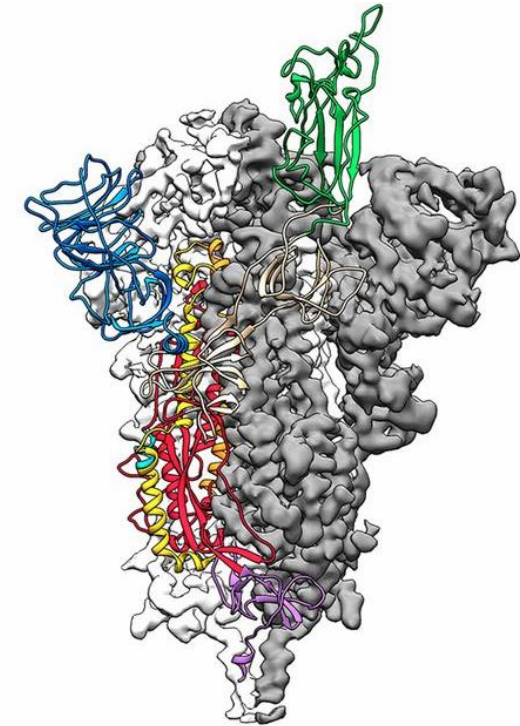


SARS-CoV-2 and its spike protein (the vaccine target)

Slide credit: Vaccine Research Center, NIAID



Spike Protein



Viral membrane

[This Photo](#) by Unknown Author is licensed under [CC BY-SA](#)

Image credit: 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. doi: 10.1126/science.abb2507.

The pieces involved - 1

- The coronavirus spike protein is on the surface of the virus. It directs how the virus attaches to cells to start the infection process.
- An ideal vaccine targets the coronavirus spikes in order to block infection.

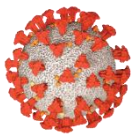
Slide credit: Vaccine Research Center, NIAID

Coronavirus

Spike Protein

Human ACE2 Receptor

Cells in Human Body



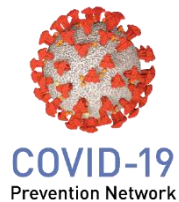
The pieces involved - 2

- The coronavirus spike protein attaches to the ACE2 receptor to start an infection.

Slide credit: Vaccine Research Center, NIAID

Coronavirus

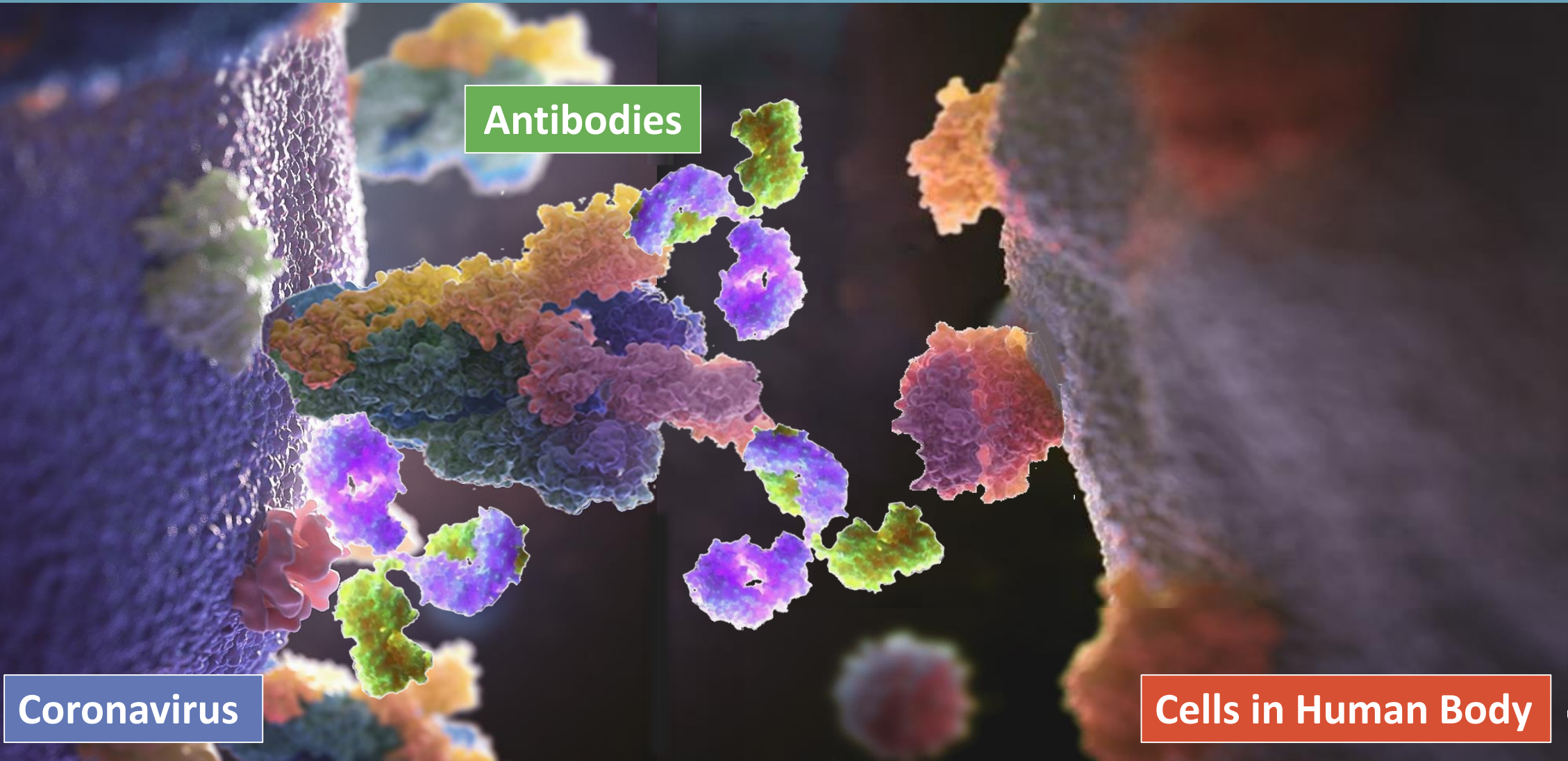
Cells in Human Body



The goal: antibodies!

- Vaccine-induced antibodies can block the spike protein from attaching to human cells.

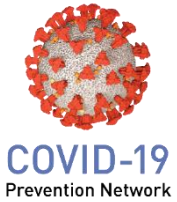
Slide credit: Vaccine Research Center, NIAID



Antibodies

Coronavirus

Cells in Human Body



Stages of clinical trials

PHASE 1

Trials to test safety and whether the body can tolerate the product. Often involves comparing against a placebo with no active ingredients. **Usually less than 100 people.**

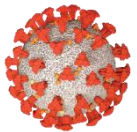
PHASE 2

Identifying the maximum tolerated dose, the best dosing schedule, and if the immune system is having the desired responses. **Usually a few hundred to a few thousand people.**

PHASE 3

“Does this product prevent infections, or help to reduce the severity of disease?” **Involves thousands of people, including some at risk of infection.**

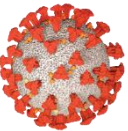
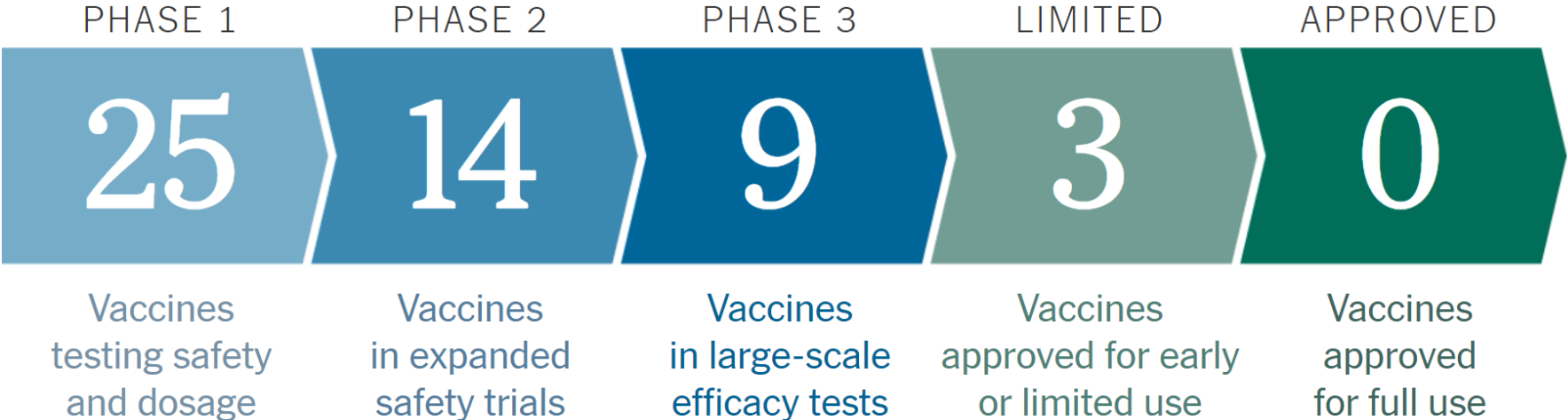
With SARS-CoV-2, we are working as quickly as possible. **No phases are skipped.** Instead, we overlap the phases, starting the next phase as quickly as we have the necessary safety data collected and analyzed from the earlier phase. The new phase can start while the long-term follow-up of people in the earlier phase continues. Other steps can be done in parallel, instead of one after the other.



Number of vaccines in development

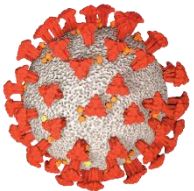
Coronavirus Vaccine Tracker

By Jonathan Corum, Denise Grady, Sui-Lee Wee and Carl Zimmer Updated September 10, 2020

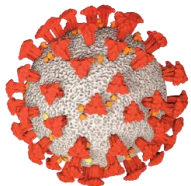
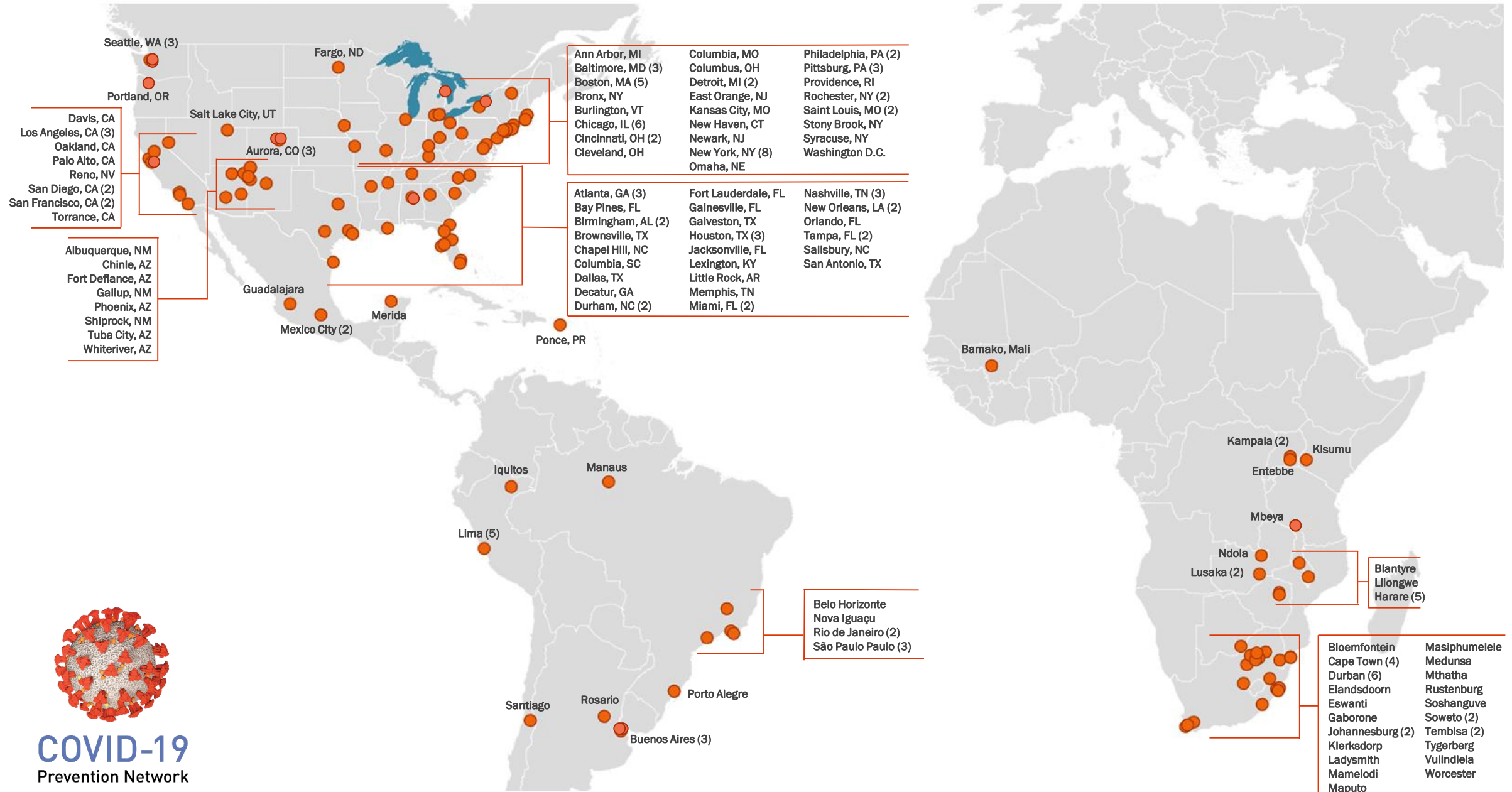


COVID-19 Prevention Network (CoVPN)

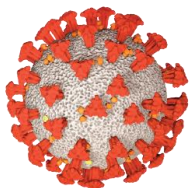
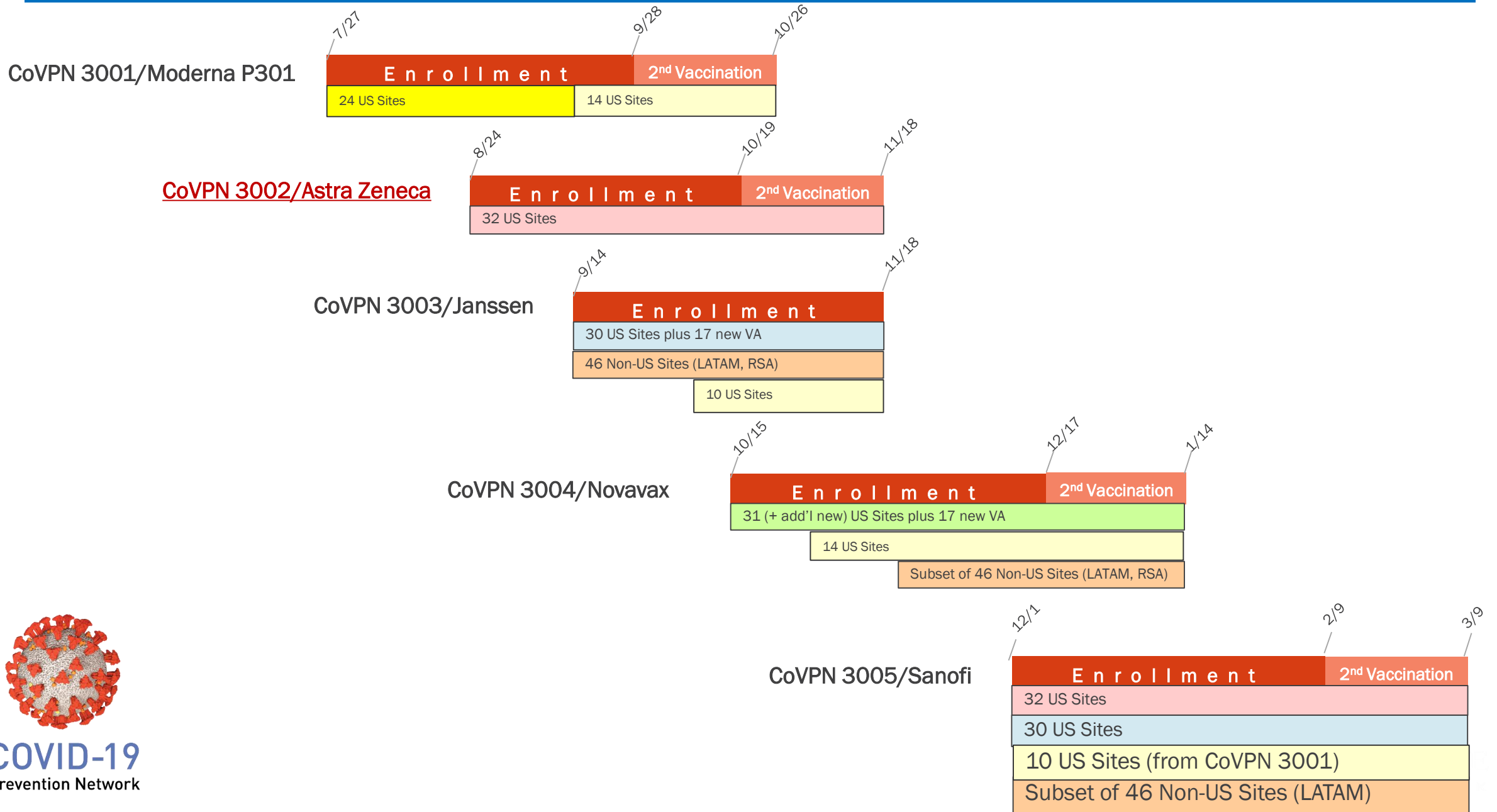
- **Formed by NIAID at NIH**
 - Global network of NIAID sites and Clinical Research Organization sites, as needed
 - Links together multiple NIH-sponsored networks
 - Local sites include Bridge HIV (SFDPH), UCSF/ZSFG, EBAC (Oakland)
- **Mission: To conduct Phase III efficacy trials to prevent infection and COVID-19 disease**
- **Plan to open 5 Phase III vaccine efficacy trials in 2020, each roughly 30,000**
- **Also plan several monoclonal antibody efficacy trials, may be smaller**
 - Some focus on Nursing Homes, Skilled Nursing Facilities
 - Others focus on household contacts of newly diagnosed COVID-19 patients



NIAID COVID-19 Prevention Network, N=189 (as of 8/1/2020)



Strategy for CoVPN Vaccine Efficacy Trials

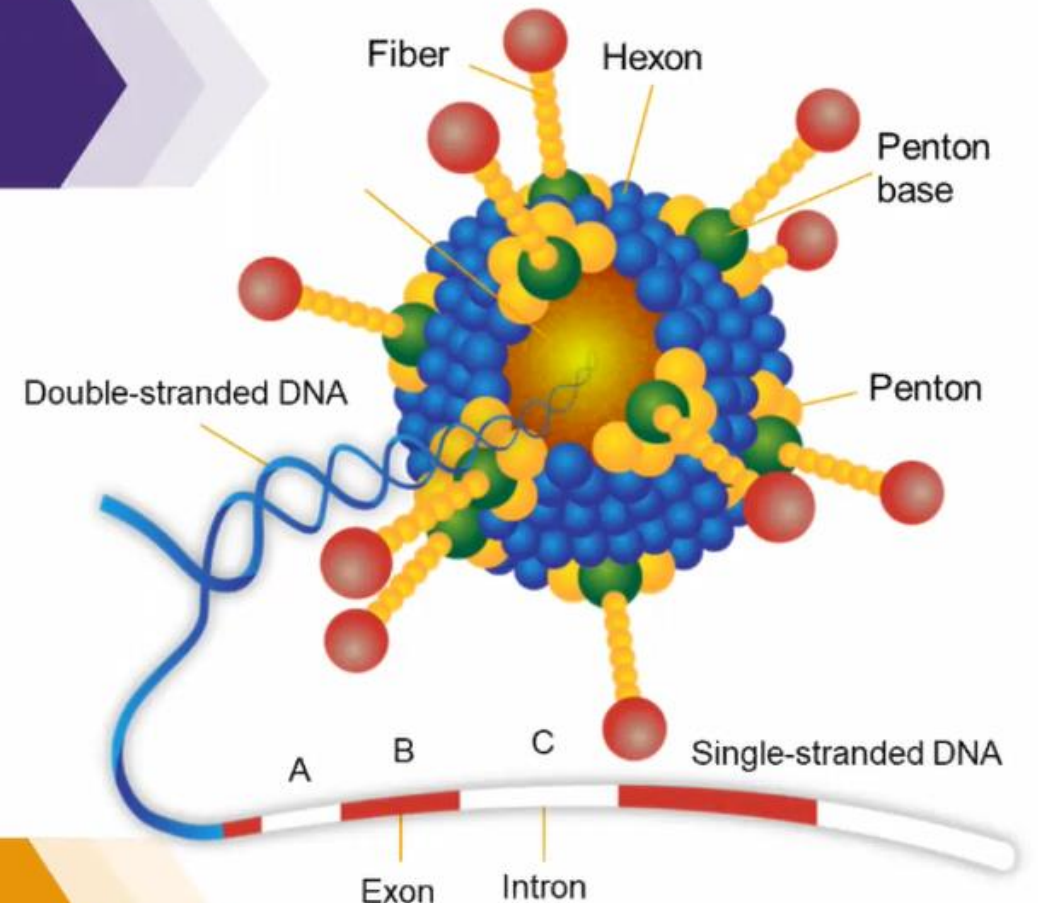


AZD1222/ChAdOx1 nCov-19: The Technology behind the Vaccine Candidate

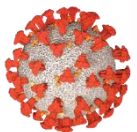
Based on existing simian recombinant adenovirus vaccine vector (ChAdOx1)

- Can not cause infection or disease in humans
- Simian Adenovirus (causes the common cold in chimpanzees).
- Triggers a strong immune response (antibodies and immune cells) in people
- Safe in early clinical (phase I and II) trials
- ChAdOx1 nCov-19 was developed by University of Oxford and has been used in 14 studies

Contains genetic material of the SARS CoV-2 spike protein

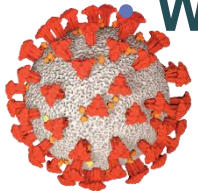


AZD1222
COVID-19 VACCINE STUDY



AstraZeneca Phase III vaccine efficacy trial

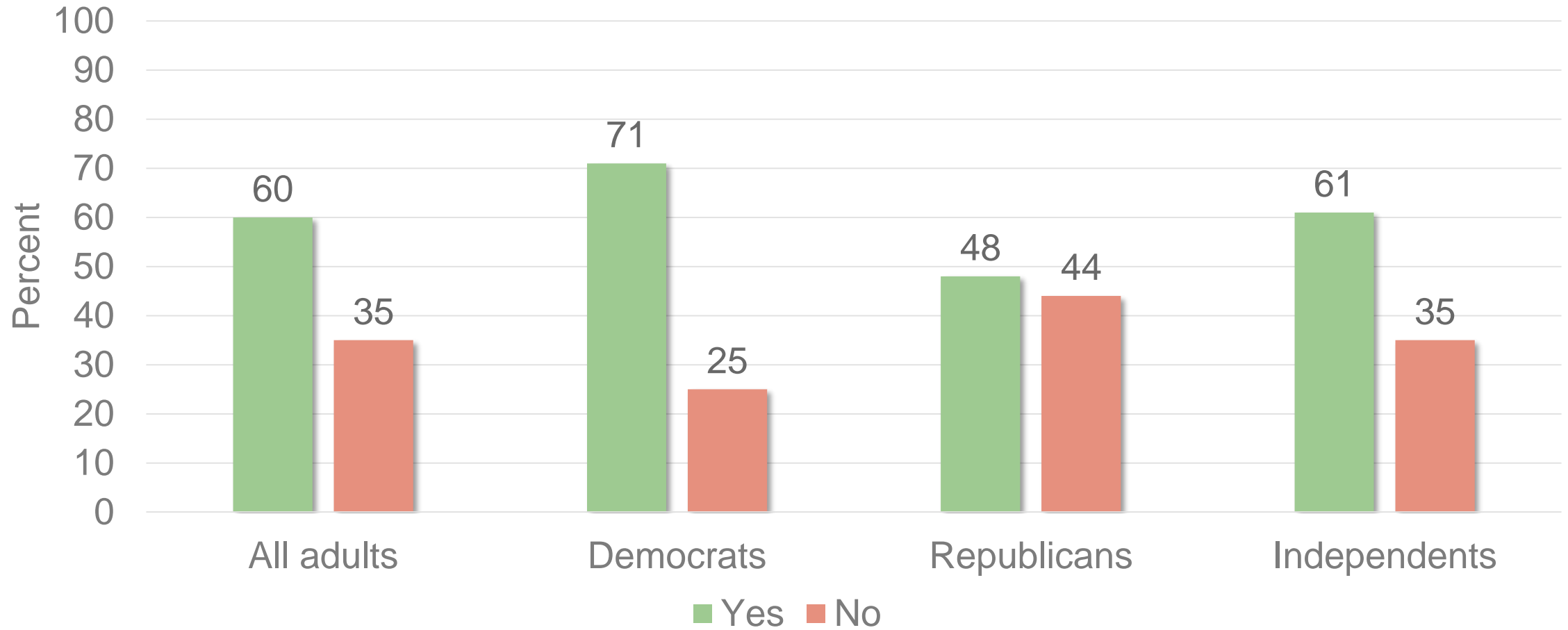
- **Launched August 28, 2020; recruitment planned for 8 weeks**
- **30,000 participants**
 - 20,000 will get the vaccine, 10,000 will get the saline placebo
 - Target 250 at each of the SF sites, 250 in Oakland
 - Participants at risk for COVID-19 disease
 - Very broad eligibility criteria (medically stable, able to get injections and blood draws, able to fully participate in trial)
 - Excluded: children, pregnant and breastfeeding women, people with prior known SARS-CoV-2
- **Two doses, 1 month apart**
- **6 visits in the first year, 1 final visit at 2 years**
- **Weekly surveillance for symptoms**
 - If symptomatic with any COVID-type symptoms, come in for diagnosis and specimen collection
 - Home electronic monitoring to measure blood oxygen, heart rate, temp, activity
 - Home collection of saliva specimens



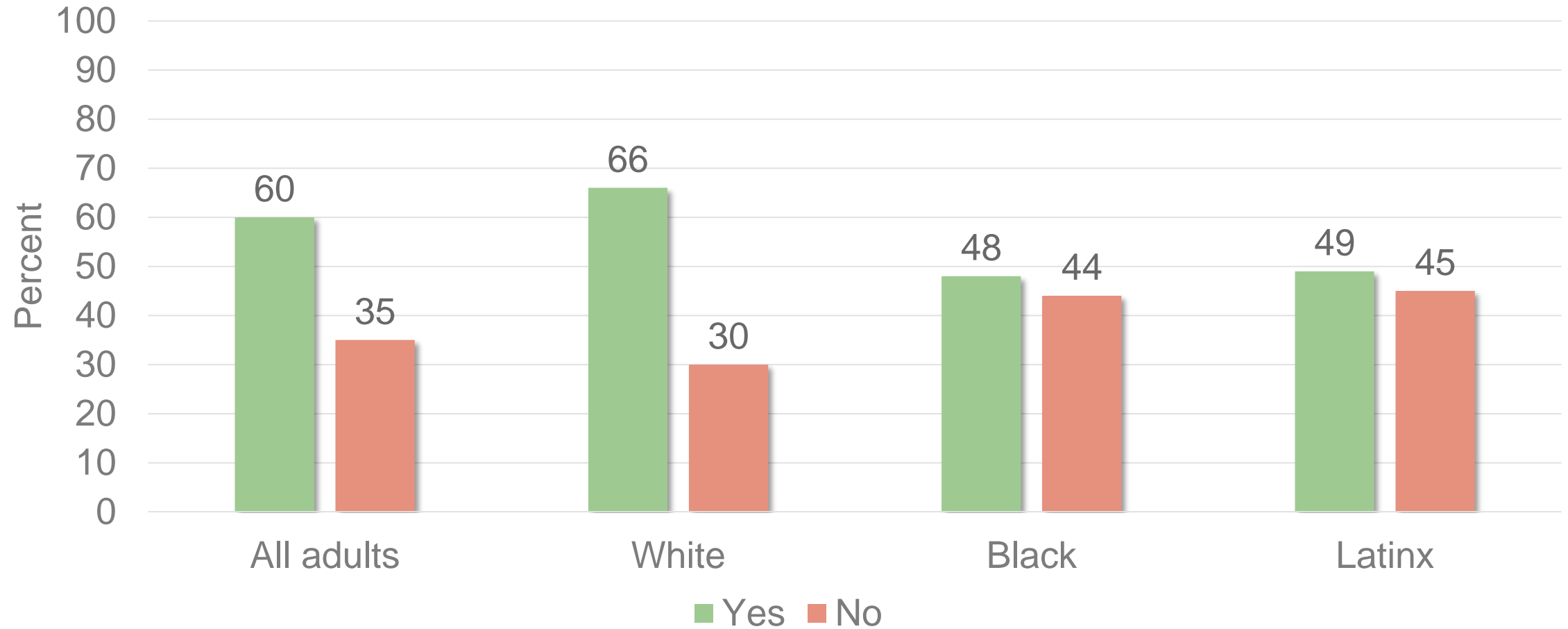
Anti-COVID vaccine



“If a vaccine for the coronavirus is made available to you, will you choose to be vaccinated or not?”



“If a vaccine for the coronavirus is made available to you, will you choose to be vaccinated or not?”



Community Engagement

- **Locally, conducting series of listening sessions and town halls with CBOs, clinics, and community members**
- **Launched website: wecanbeatcovid.org; combatimoscovid.org**
- **Nationally,**
 - Coronavirus Prevention Network Website (coronaviruspreventionnetwork.org)
 - Campaigns with spokespeople, advertisements
 - Faith-based initiative

Recruitment strategies

- **Want to ensure that recruited population reflects the local/national epidemic**
 - By race/ethnicity
 - By age ($\geq 25\%$ age ≥ 65 years)
 - Essential workers
 - SNFs, SROs
 - Other people potentially exposed

Interested in volunteering for a COVID-19 Prevention Clinical Study?

Thank you for your interest in our studies. Science can't move forward without your help!

Selecting the button below will take you to the CoVPN Volunteer Screening Registry.

The purpose of this screening registry is to create a list of potential volunteers who want to take part in current or future COVID-19 prevention clinical trials. You must be 18 years or older to participate. Participation involves completing a short online survey that includes some personal questions. Your participation is voluntary.

[Volunteer Now!](#)

>9000 people have signed up in SF Bay Area



Our studies enroll adults aged 18 and older, of all races and ethnicities, and of all gender identities.

Credit: iStock

