OPERATION WARP SPEED:

Overview of COVID Vaccine Efficacy Trials

JULY 29, 2020

Julie Ledgerwood, DO
Deputy Director,
Chief Medical Officer,
Vaccine Research Center
National Institute of Allergy and Infectious Diseases
National Institutes of Health

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

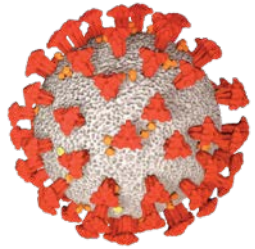
Three Entities with Distinct Roles in COVID-19 Response

Operation Warp Speed

USG body responsible for strategic approach, coordination and resource allocation

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

NIH established Public-private partnership for coordinating COVID-19 response



COVID-19 Prevention Network

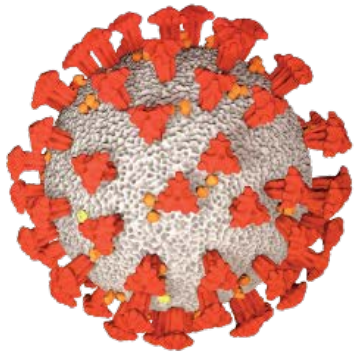
NIH Funded networks - Phase 3 trial execution

Conducting Clinical Research: A Network Approach

HIV VACCINE TRIALS NETWORK

IDCRC
Infectious Diseases Clinical Research Consortium

HPTN
HIV Prevention Trials Network



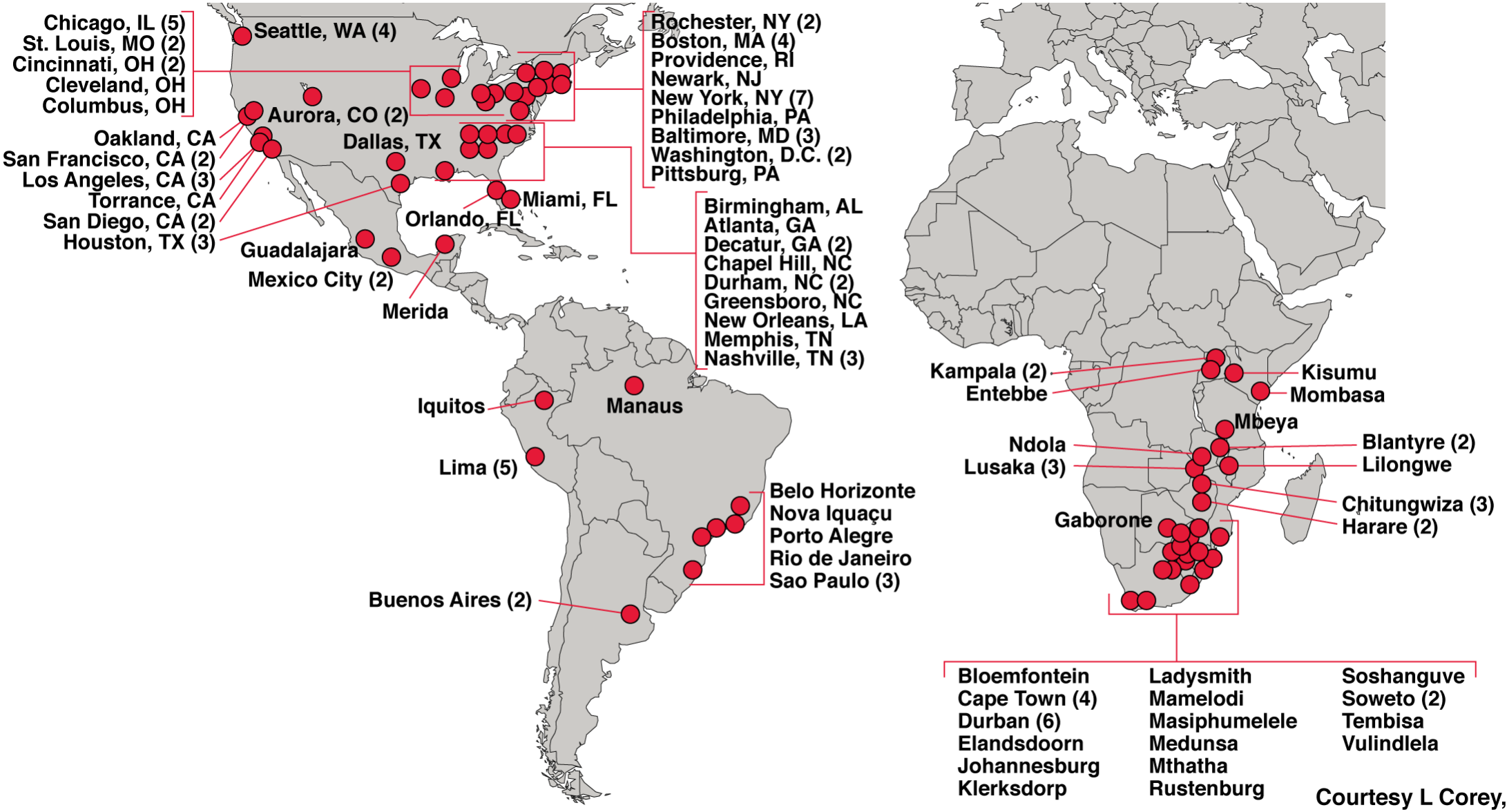
COVID-19 Prevention Network

(CoVPN)

Vaccine Efficacy Trials
- Larry Corey and Kathy Neuzil

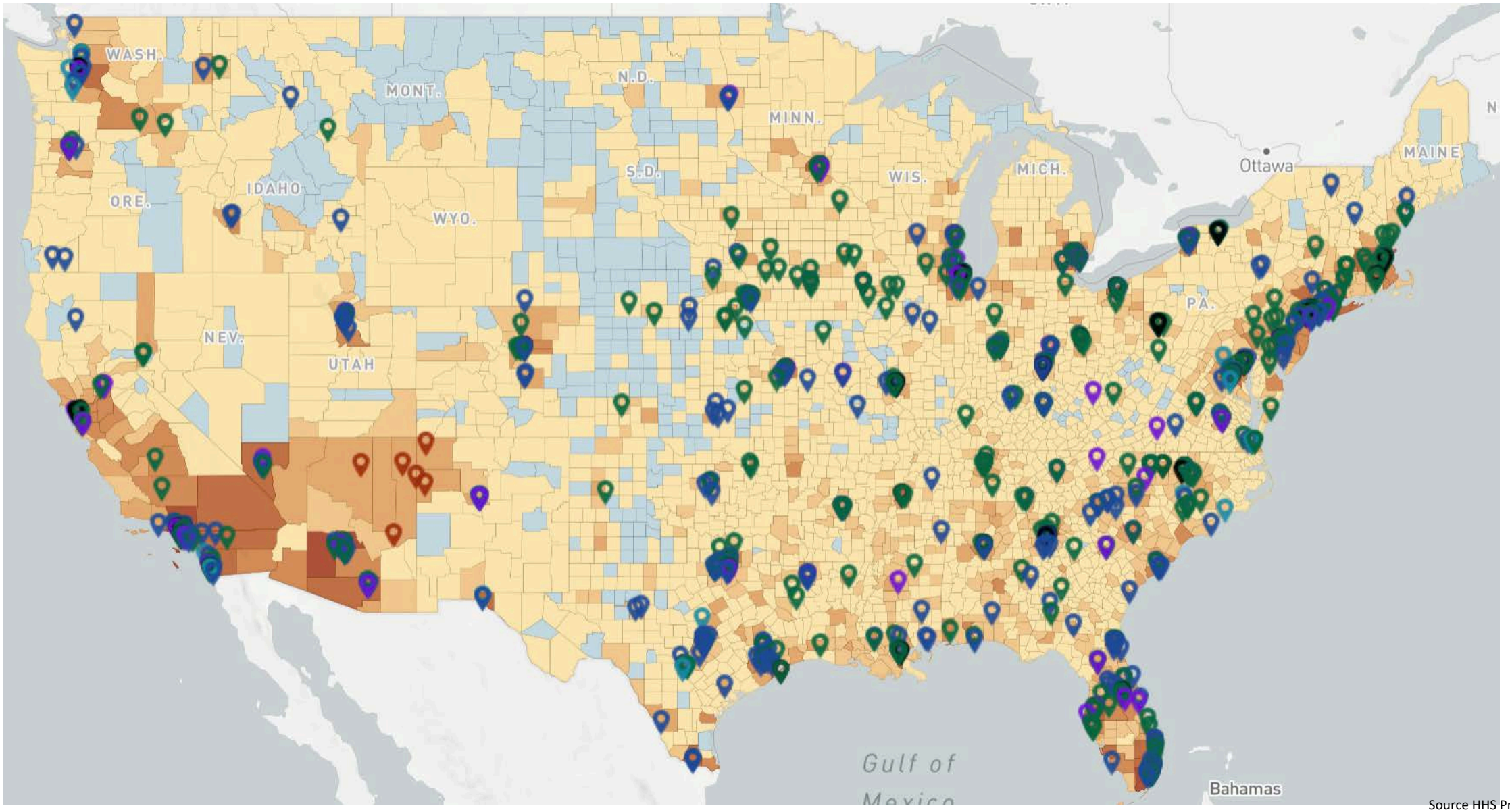
mAb Prevention Trials
- Mike Cohen and David Stephens

CoVPN Clinical Sites



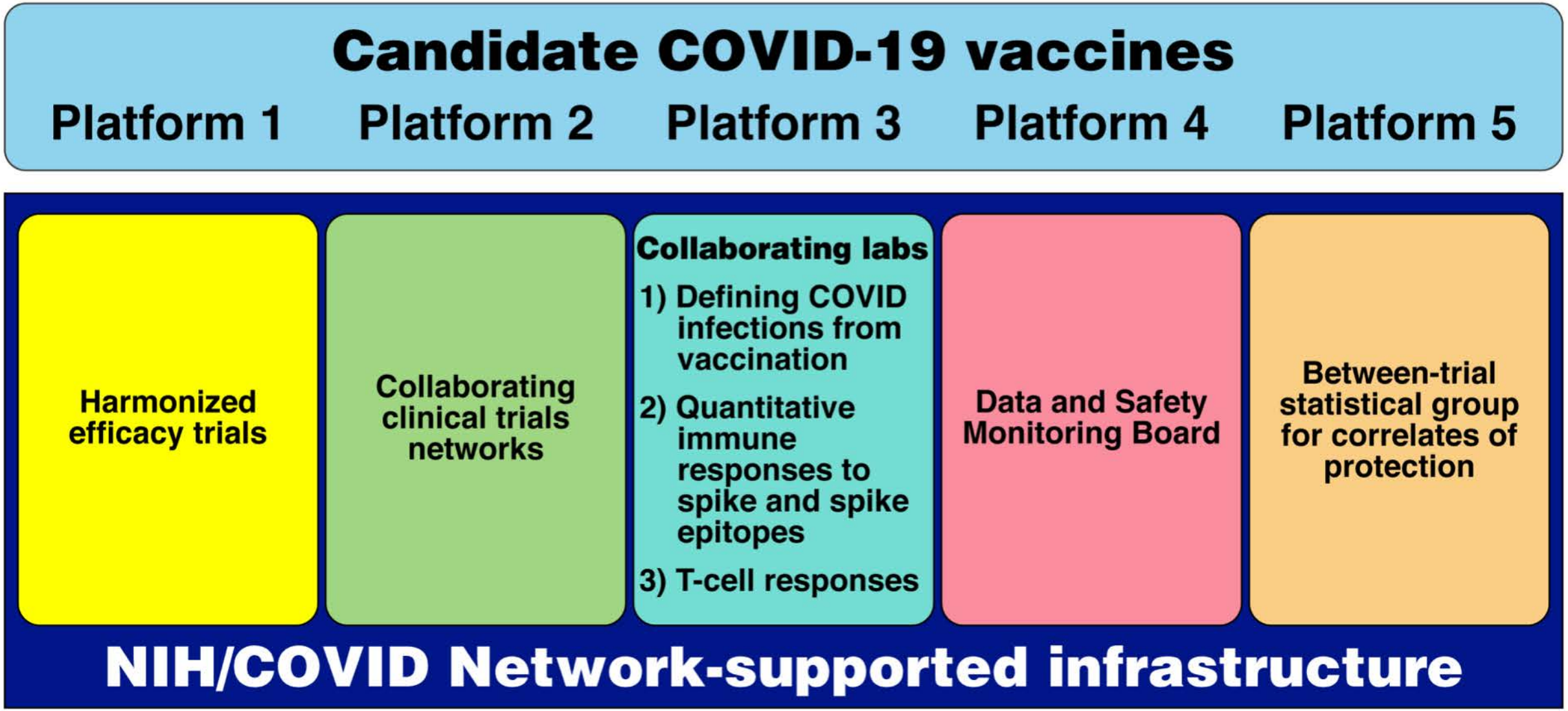
Courtesy L Corey, HVTN

Potential CoVPN, DoD and CRO US Clinical Sites



Source HHS Protect
Data as of July 26, 2020

Semi-Independent Harmonized Trials



AS Fauci/NIAID

Development and Licensure of Vaccines to Prevent COVID-19

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic which has been caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to assist sponsors in the clinical development and licensure of vaccines for the prevention of COVID-19.

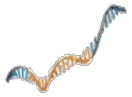
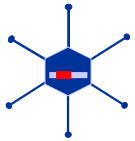
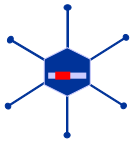
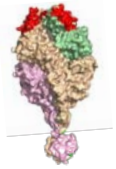
Posted June 2020
https://www.fda.gov/media/139638/download

OWS Phase 3 Efficacy Trial Principles

- Randomized, Placebo-Controlled Efficacy Trial
- Sample size: approximately 30,000 volunteers
- Study Population: age ≥ 18 years, targeting subset at higher risk of severe disease, diverse populations
- Primary Endpoint: Prevention of symptomatic COVID-19 disease (virologically confirmed)
  - The primary efficacy endpoint point-estimate at least 50%
  - the statistical success criterion should be lower bound of the CI confidence around the point estimate is >30%.*
- Harmonized OWS immunogenicity assays and correlates analysis
- Common DSMB (NIAID Managed)

*Consistent with FDA guidance, June 2020

COVID-19 Vaccines in OWS Development

Vaccine companies Participating in OWS Led BARDA & NIH Funded Phase 3 Efficacy Trials			Phase 3 Open to Accrual (projected as of July 29, 2020)
moderna	mRNA		July 27, 2020
AstraZeneca	Ad Vector		TBD
janssen	Ad Vector		September 2020 (projected)
NOVAVAX Creating Tomorrow's Vaccines Today	Recombinant Protein+adjuvant		October 2020 (projected)

Monday, July 27, 2020

Phase 3 clinical trial of investigational vaccine for COVID-19 begins

Multi-site trial to test candidate developed by Moderna and NIH.

People 18 years of age and older who are interested in participating in this trial can visit https://www.coronavirusprevention network.org or ClinicalTrials.gov and search identifier NCT04470427 for details. Please do not contact the NIAID media phone number or email to enroll in this trial.

A Phase 3 clinical trial designed to evaluate if an investigational vaccine can prevent symptomatic coronavirus disease 2019 (COVID-19) in adults has begun. The vaccine, known as mRNA-1273, was co-developed by the Cambridge, Massachusetts-based biotechnology company Moderna, Inc., and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The trial, which will be conducted at U.S. clinical research sites, is expected to enroll approximately 30,000 adult volunteers who do not have COVID-19.

mRNA-1273 Phase 3

U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies | About Studies | Submit Studies | Resources | About Site

Home > Search Results > Study Record Detail

Save this study

Trial record **1 of 1** for: NCT04470427

Previous Study | Return to List | Next Study

A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19

Sponsor:
ModernaTX, Inc.

Collaborators:
Biomedical Advanced Research and Development Authority
National Institute of Allergy and Infectious Diseases (NIAID)

Information provided by (Responsible Party):
ModernaTX, Inc.

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:
The mRNA-1273 vaccine is being developed to prevent COVID-19, the disease resulting from Severe Acute Respiratory Syndrome coronavirus (SARS-CoV-2) infection. The study is designed to primarily evaluate the efficacy, safety, and immunogenicity of mRNA-1273 to prevent COVID-19 for up to 2 years after the second dose of mRNA-1273.

Condition or disease	Intervention/treatment	Phase
SARS-CoV-2	Biological: mRNA-1273 Biological: Placebo	Phase 3

Study Design

Go to

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	30000 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Prevention
Official Title:	A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older
Actual Study Start Date :	July 27, 2020
Estimated Primary Completion Date :	October 27, 2022
Estimated Study Completion Date :	October 27, 2022

Spreading the Word: Coronaviruspreventionnetwork.org

COVID-19 Prevention Network

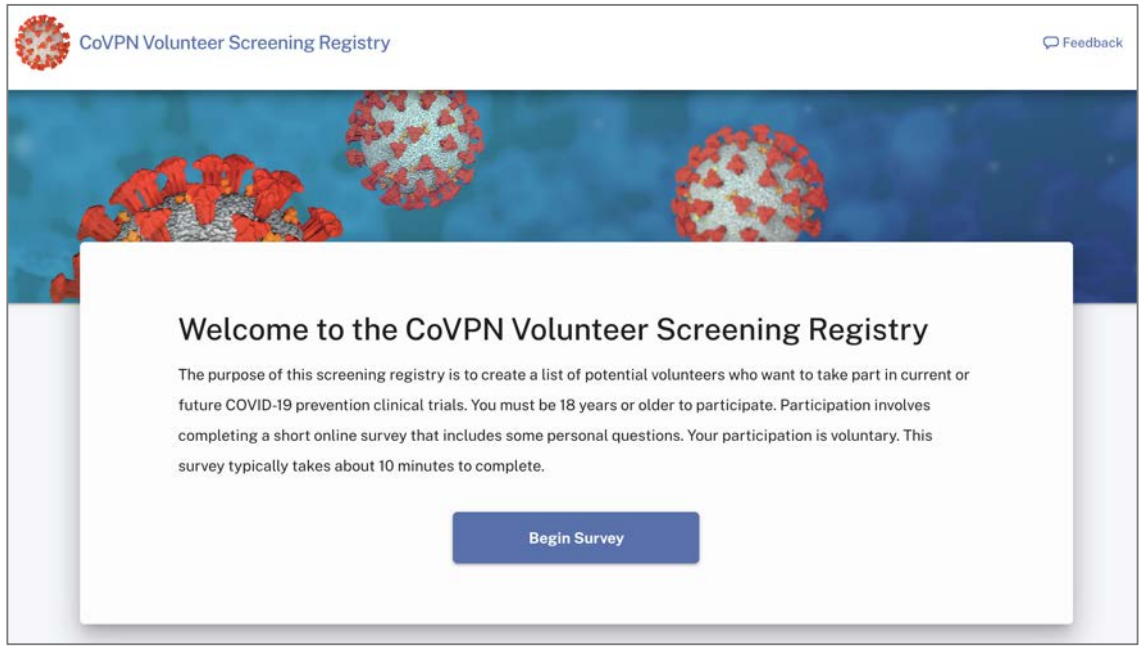
Interested in volunteering for a COVID-19 Prevention Clinical Study?

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

Volunteer Now!

Community Engagement and Volunteer Registry

Example US trial site map with broad US coverage



As of July 28, 2020

- 4.5 million views
- 200,000 completed registries in initial 20 days

- Nationwide Community Outreach and Engagement Ongoing

- Key to Recruiting High Risk Volunteers from Diverse Populations

Collaborations / Partners / Acknowledgements

- OWS Leadership
- NIH
- NIAID
- HHS
- DoD
- BARDA
- CDC
- FDA
- CoVPN
- Industry Partners and CROs