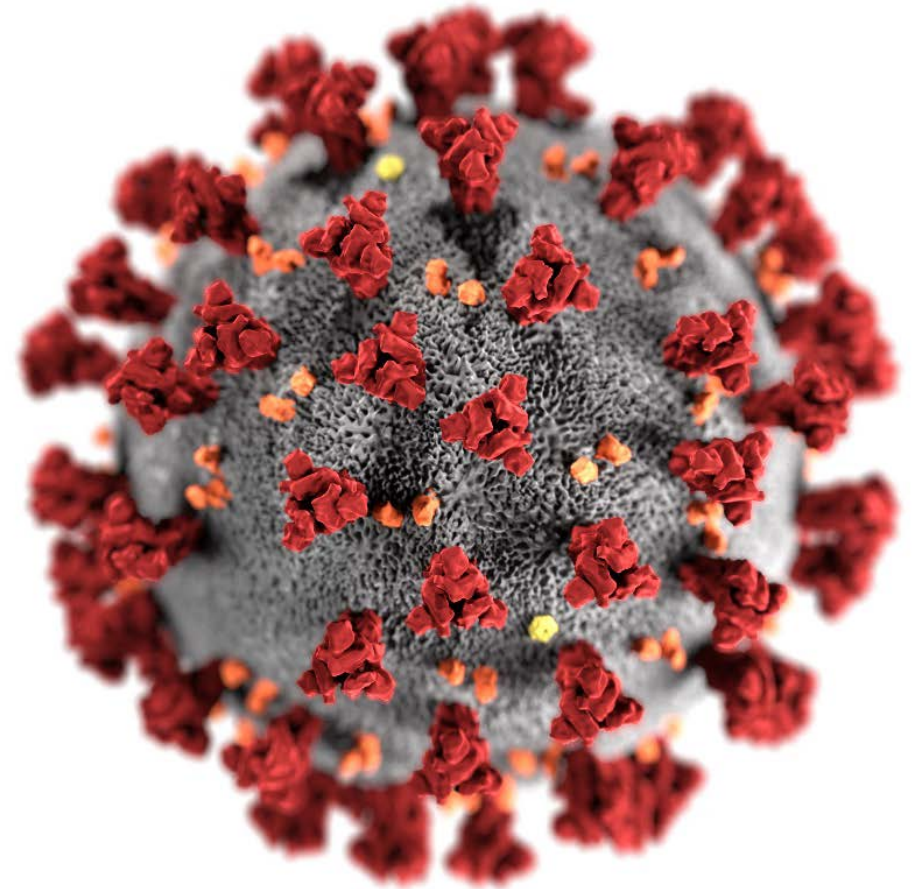


# ACIP COVID-19 Vaccines Work Group

**Dr. Beth Bell, Work Group Chair**

**November 23, 2020**



# Background

- ACIP responding to ongoing pandemic and accelerated vaccine development through scheduling of additional ACIP meetings
- At the October 30<sup>th</sup> meeting, ACIP reviewed:
  - Updates from VRBPAC meeting
  - Development program from 2 COVID-19 vaccine manufacturers
  - Updates on vaccine implementation and communication plans
  - Post-authorization safety monitoring
  - Ethical principles and modeling strategies for initial allocation of COVID-19 vaccines
  - Updates to immunity and epidemiology
  - Work Group interpretation of data
  - Policy questions, Evidence to Recommendation Framework and Outcomes

# COVID-19 Work Group activities – October 2020

- COVID-19 Vaccine Work Group meets weekly
  
- Topics covered in November:
  - Ethical principles for allocating initial supplies of COVID-19 vaccine
  - Current evidence for each domain in Evidence to Recommendation Framework
  - Further discussions around initial allocation recommendations

# Today's agenda

- **EtR Framework: Public Health Problem, Resource Use and Equity Domains:**  
Dr. Sara Oliver (CDC)
- **EtR Framework: Values, Acceptability and Feasibility Domains:**  
Dr. Sara Oliver (CDC)
- **Phased Allocation of COVID-19 Vaccines:**  
Dr. Kathleen Dooling (CDC)

# Vaccine Update

- Over 200 COVID-19 vaccines currently under development
- Within the United States:
  - **Four** vaccines in Phase III clinical trials
  - **Six** vaccines in Phase I/II clinical trials

# Phase III Results from Two mRNA Vaccines

- BNT162b2 vaccine (Pfizer/BioNtech)
  - Final analysis of **170** cases
    - 162 cases in placebo group
    - 8 cases in vaccine group
  - **95%** effective 7 days post dose 2
  - **94%** effective in adults  $\geq 65$  years of age
  - 10 severe cases, 9 in placebo group
  - DSMB: no serious safety concerns
  - EUA submission Friday Nov 20, 2020
- mRNA-1273 vaccine (Moderna)
  - Interim analysis of **95** cases
    - 90 cases in placebo group
    - 5 cases in vaccine group
  - **94.5%** effective 2 weeks post dose 2
  - 11 severe cases, all in placebo group
  - DSMB: no serious safety concerns
  - EUA submission soon

\*Information from manufacturer press releases

# COVID-19 vaccines in human clinical trials – United States\*

Candidate	Manufacturer	Type	Phase	Schedule	Age	Size	Trial #	Recruiting
mRNA-1273	Moderna	mRNA	III	2 doses (0, 28d)	≥18 years	30,000 participants	NCT04470427	Enrollment complete
mRNA-BNT162	Pfizer, Inc./ BioNTech	mRNA	III	2 doses (0, 21d)	12-85 years	44,000 participants	NCT04368728	✓
AZD1222	U of Oxford/ AstraZeneca	Viral vector (Non-replicating)	III	2 doses (0, 28d)	≥18 years	40,000 participants	NCT04516746	✓
Ad26COVS1	Janssen	Viral vector (Non-replicating)	III	1 dose	≥18 years	30,000 participants	NCT04614948	✓
NVX-CoV2373	Novavax	Protein Subunit	I/II	2 doses (0, 21d)	18-84 years	1400 participants	NCT04368988	Enrollment complete
--	Sanofi/GSK	Protein Subunit	I/II	1 dose or 2 doses (0, 21d)	≥18 years	440 participants	NCT04537208	✓

\*As of Nov 21, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccineshinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccineshinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



# COVID-19 vaccines in human clinical trials – United States\*

Candidate	Manufacturer	Type	Phase	Schedule	Age	Size	Trial #	Recruiting
V591	Merck	Viral Vector (Replicating)	I/II	2 doses (1, 57d)	≥18 years	260 participants	NCT04498247	✓
VXA-CoV2-1	Vaxart	Viral vector (Non-replicating)	I	2 doses (1, 29d) *Oral	18-54 years	48 participants	NCT04563702	✓
INO-4800	Inovio	DNA plasmid	I	2 doses (0, 4w) *Electroporation	≥18 years	120 participants	NCT04336410	Active, not recruiting
AV-COVID-19	Aivita	AuDendritic cell	I/II	1 dose	≥18 years	180 participants	NCT04386252	Not yet recruiting

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Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccines.shinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccines.shinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>





# COVID-19 vaccines in human clinical trials outside United States – Phase III actively recruiting\*

## Inactivated Vaccines

*4 inactivated vaccines candidates are in Phase I/II*

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
BIBP/Sinopharm BBIBP-CorV	Beijing Institute of Biological Products/Sinopharm	Inactivated	Argentina	Phase III	NCT04560881
Sinovac CoronaVac	Sinovac/Instituto Butantan	Inactivated	Turkey, Brazil, Indonesia	Phase III	NCT04582344; NCT04456595; NCT04508075
WIBP vaccine	Wuhan Institute of Biological Products/Sinopharm	Inactivated	Morocco	Phase III	ChiCTR2000039000
WIBP/BIBP/Sinopharm vaccines	Beijing Institute of Biological Products/Wuhan Institute of Biological Products/Sinopharm	Inactivated	UAE, Bahrain, Jordan, Egypt	Phase III	NCT04510207

## Protein Subunit Vaccines

*11 protein subunit vaccines candidates are in Phase I/II*

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
Novavax NVX-CoV2373	Novavax	Protein subunit	UK	Phase III	NCT04583995

\*As of Nov 21, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccineshinyapps.io/ncov\\_vaccine\\_landscape/](https://vaccineshinyapps.io/ncov_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



# COVID-19 vaccines in human clinical trials outside United States – Phase III actively recruiting\*

## Viral Vector Vaccines (non-replicating)

*7 non-replicating viral vector vaccines candidates are in Phase I/II*

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
Cansino Ad5-nCoV	CanSino Biological Inc/ Beijing Institute of Biotechnology	Non-replicating viral vector	Pakistan, Russia	Phase III	NCT04526990; NCT04540419
Gamaleya Gam-COVID- Vac	Gamaleya Research Institute	Non-replicating viral vector	Belarus, Russia	Phase III	NCT04530396; NCT04564716
Janssen Ad26.COV2.S	Janssen Pharmaceutical Companies	Non-replicating viral vector	USA, Argentina, Brazil, others	Phase III	NCT04505722
Oxford ChAdOx1-S	University of Oxford/AstraZeneca	Non-replicating viral vector	UK, Brazil, India, South Africa	Phase II/III	NCT04400838; NCT04536051; CTRI/2020/08/027170

## RNA Vaccines

*7 RNA vaccines candidates are in Phase I/II*

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
BioNTech BNT162 (b1/b2)	BioNTech/Fosun Pharma/Pfizer	RNA	USA, Argentina, Brazil, others	Phase II/III	NCT04368728



\*As of Nov 21, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker/>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; [https://vaccineshinyapps.io/nCoV\\_vaccine\\_landscape/](https://vaccineshinyapps.io/nCoV_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

# Work group members

## ACIP members

- Beth Bell (chair)
- Grace Lee
- Jose Romero
- Keipp Talbot

## Ex-officio/government members

- FDA: Doran Fink, Rachel Zhang
- NIH: Chris Roberts
- IHS: Thomas Weiser, Jillian Doss-Walker
- DOD: Bryan Schumacher
- CMS: Jeff Kelman
- BARDA: Christine Oshansky
- HHS: David Kim

## CDC Co-leads

- Kathleen Dooling
- Sara Oliver

## Liaisons

- AAFP: Jonathan Temte
- AAP: Sean O'Leary
- ACOG: Denise Jamieson (primary), Laura Riley (alternate)
- ACP: Jason Goldman
- AGS: Ken Schmader
- AIM: Rob Shechter (primary), Jane Zucker (alternate)
- AMA: Sandra Fryhofer
- ANA: Kendra McMillan (primary), Ruth Francis (alternate)
- APhA: Michael Hogue
- ASTHO: Marcus Plescia
- CSTE: Susan Lett
- IDSA: Jeff Duchin (primary), Carol Baker (alternate)

## Liaisons, cont'd

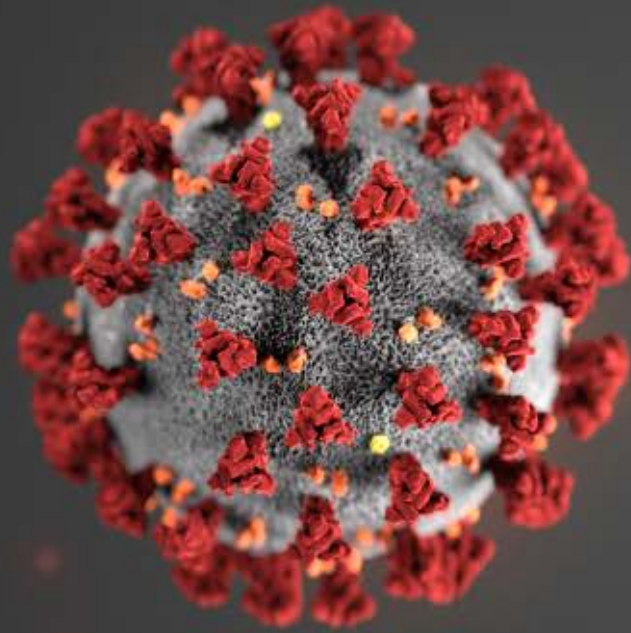
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis (primary), Linlu Zhao (alternate)
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

## Consultants

- Ed Belongia (safety)
- Matthew Daley (safety)
- Kathy Kinlaw (ethics)
- Dayna Matthew (health equity)
- Kathleen Neuzil (vaccinology)
- Stanley Perlman (microbiology/immunology)

# CDC participants

- Doug Campos-Outcalt
- Mary Chamberland
- Thomas Clark
- Amanda Cohn
- Jean Cox-Ganser
- Katie Curran
- Jonathan Duffy
- Anthony Fiore
- Mark Freedman
- Sue Gerber
- Jack Gersten
- Susan Goldstein
- Sam Graitcer
- Lisa Grohskopf
- Rita Helfand
- Terri Hyde
- Tara Jatlaoui
- Cynthia Jorgensen
- Erin Kennedy
- Ram Koppaka
- Jessica MacNeil
- Sarah Mbaeyi
- Nancy McClung
- Lucy McNamara
- Rebecca Morgan
- Titilope Oduyebo
- Christina Ottis
- Anita Patel
- Janell Routh
- Stephanie Schrag
- Tom Shimabukuro
- Natalie Thornburg
- Jennifer Verani
- Megan Wallace
- Cindy Weinbaum
- Yon Yu
- Jane Zucker



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

# Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

