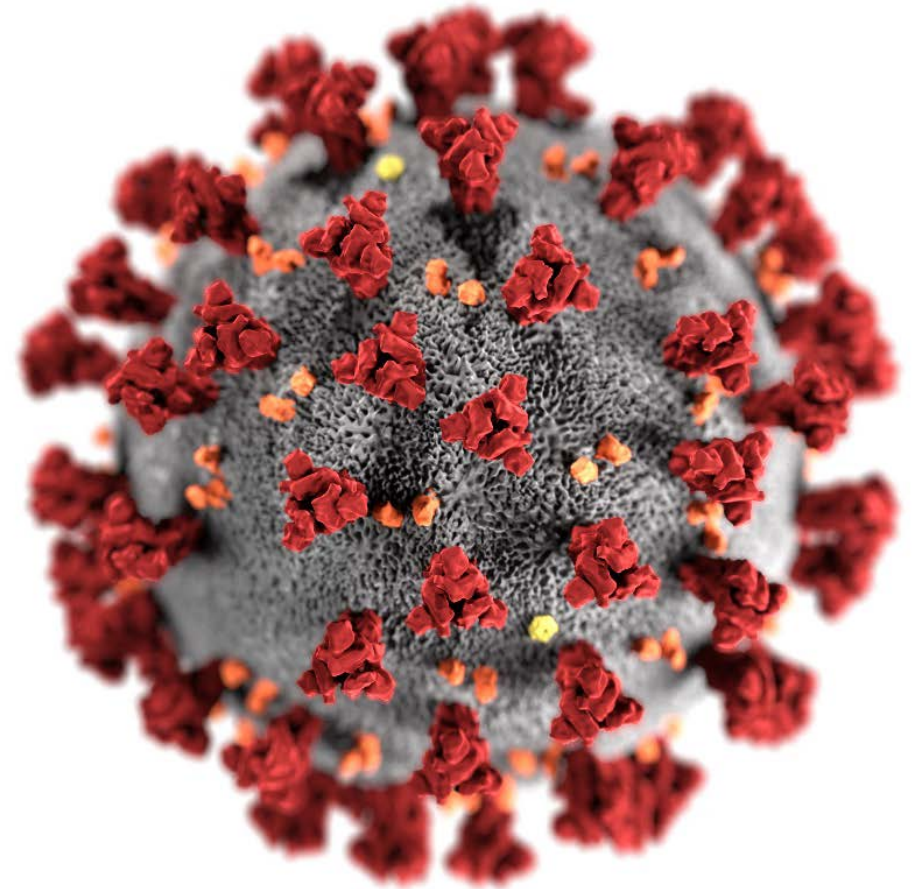


ACIP COVID-19 Vaccines Work Group

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 30th 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 ≥ 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://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

*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://vaccine.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://vaccine.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*

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://vaccines.shinyapps.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

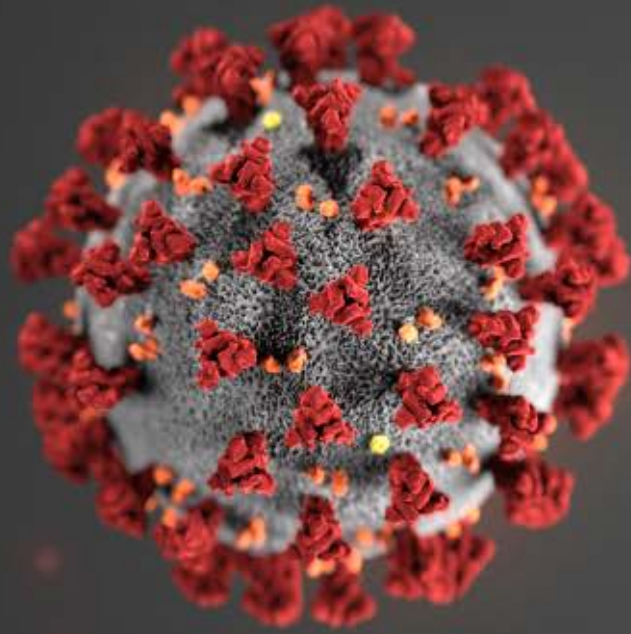
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis (primary), Linlu Zhao (alternate)
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

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

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.

